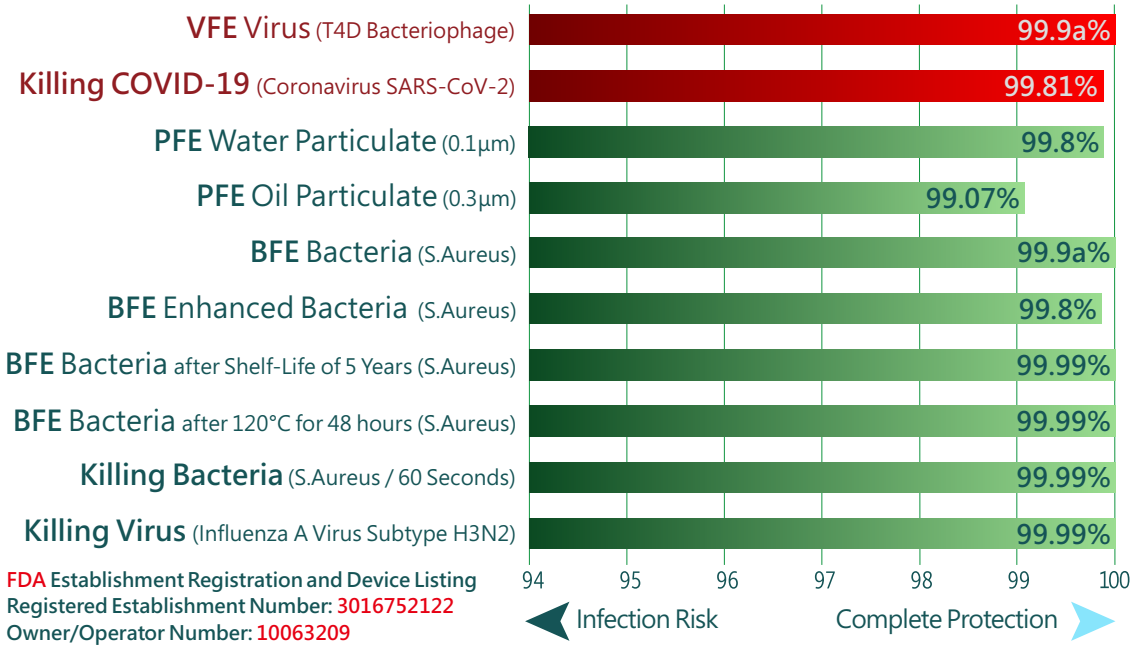
Curie

KV99 COVID-19 Killing Surgical Mask

VFE > 99.9a% / Killing COVID-19 99.81%

Efficiency



FDA Establishment Registration and Device Listing
Registered Establishment Number: 3016752122
Owner/Operator Number: 10063209

Viral Filtration Efficiency 99.9a% / Killing COVID-19 99.81%

Properties

Test	
Differential Pressure (mmH₂O)	5
Fluid Resistance (mmHg)	160
Flame Spread (Second)	5
Microbio Cleanliness (cfu)	< 6
Shelf Life (Year)	5

ASTM F2101 Level 3
US Medical Face Masks Standard

EN14683 TYPE IIR
EU Surgical Masks Standard

Core Filtration Material - Made in Taiwan / Hong Kong

Formula - Food Additives Approved by World Health Organization (WHO)

OOH technology pass chemical safety standards for baby textile products on
EN ISO 21084:2019
EN ISO 18254:2016
EN ISO 14184:2011
JIS L 1041
DIN EN ISO 17070:2015
64 LFBG B 82.02-08
EN ISO 14389: 2014
US CPSC-CH-C1001-09.4

Production process is determined to be a non-hazardous process according to EU Dangerous Preparation Directive 1999/45/EC

FDA · National Institute for Occupational Safety and Health · NIOSH · CE · Health Canada · Australian Government Department of Health Therapeutic Goods Administration · Australian Standard · JAS-ANZ · ANVISA

FDA Taiwan FDA Approved · CCCMHPIE · KOTITI Testing & Research Institute · ISO 9001 · ISO 14001 · ISO 13485 · intertek Total Quality. Assured. · Intertek · Nelson Labs A Sotera Health company · Bureau Veritas

TTRI Taiwan Textile Research Institute · 广东省微生物分析检测中心 Guang Dong Detection Center Of Microbiology · ilac-MRA · CNAS · ATCCR · 善通 · 香港公開大學 The Open University of Hong Kong

Curie

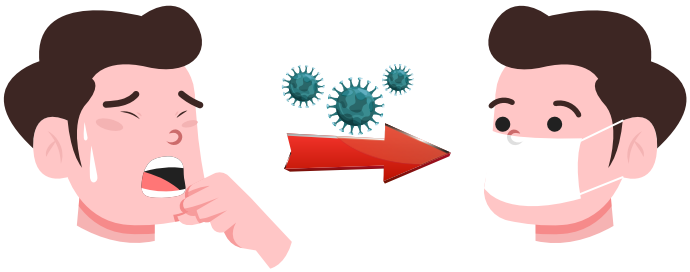
KV99 Flat Mask

KV99 3D Mask

KV99 Cup Mask

- The first Face Masks proven to **kill COVID-19 (99.81%)**
- Combined with Viral Filtration Efficiency **VFE (>99.9a%)**
- Over **500 times more effective** than traditional masks

Primary Infection



Breathing : > 1,000 COVID-19 viruses

Coughing : > 1,000,000 COVID-19 viruses

Infection : Breathing in > 100 active COVID-19 viruses

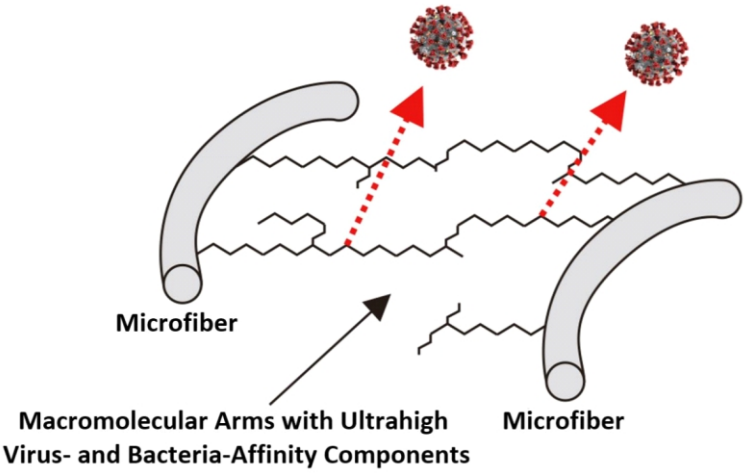
Type of Mask	No of Virus Penetrating Mask	
	Breathing	Coughing
VFE 95%	>50	>50,000
VFE 99%	>10	>10,000
Curie	>1	>10

Secondary Infection

- Viruses can survive on the surface of traditional masks for 7 days
- Viruses can grow 180 times more after 4 hours of usage
- We get infected by touching masks when they are full of viruses
- We bring masks with viruses back home, and cause secondary infection in our home environment
- A COVID-19 killing mask can fully protect against secondary infection

Curie

How We Arrest and Kill COVID-19

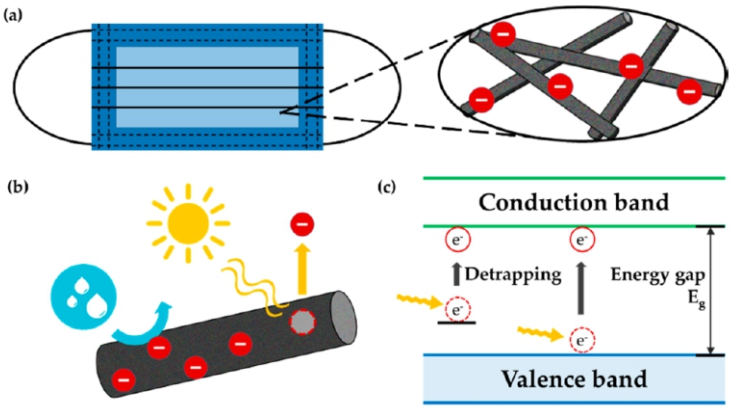


Spike protein over coronavirus is “strong negative charged”.

The highly positive-charged fibers inside Curie's filtration material attracts and arrests “strong negative charged” protein spikes on virus and bacteria

Strong attraction force can tear off protein chain over envelope of coronavirus, and achieve COVID-19 killing effect.

Shortcoming of Traditional Mask



Meltblown cloth relies on electrostatic to capture bacteria and viruses. Surface proteins of bacteria and viruses are negative-charged, and the electrostatic itself is negative. The polarity of the two is the same and therefore it repels – inefficient in capturing microbials.

Electrostatic itself is unstable, and it is easy to dissipate and discharge due to high temperature and humidity. Few hours after the mask used, the filtration efficiency begins to decay.

Curie

KV99 Flat Mask

(3M Nexcare Alternative)

Article No	: KV99-1
Product Name	: Curie Disposable Surgical Face Mask
Standard Applied	: EN14683 Type IIR / ASTM Level 3 / YY0469-2011
Specification	: Flat, Ear-Loop Mask, 17.5cmX9.5cm
Material	: 34% Positive Charged Biohazard Filter 22% Meltblown Non-Woven / 44% Non-Woven Fabric

Main Performance:

1) Particulate Filtration Efficiency (PFE)	: > 99%
2) Bacterial Filtration Efficiency (BFE)	: > 99.99%
3) Viral Filtration Efficiency (VFE)	: > 99.9a%
4) Bacterial Killing Rate	: > 99.99%
5) H3N2 Killing Rate	: > 99.99%
6) COVID-19 Killing Rate	: 99.81%
7) Differential Pressure	: < 5mmH20
8) Splash Resistance Pressure	: < 160mmHg
9) Microbial Cleanliness	: < 30cfu/g
10) Flame Spread	: < 5 Seconds
11) Shelf Life	: 5 Years
Packing Details	: 1 Carton X 40 Boxes X 50 Pieces
Carton Size	: 570mm X 390mm X 420mm
Gross Weight	: 9.2kg

KV99 3D Mask

(3M 1870 Alternative)

Article No	: KV99-2
Product Name	: Curie Disposable Foldable Respirator
Standard Applied	: EN149 FFP2 / EN14683 Type IIR / ASTM Level 3
Specification	: Foldable, 10.7cm X 16cm
Material	: 34% Positive Charged Biohazard Filter 22% Meltblown Non-Woven / 44% Non-Woven Fabric

Main Performance:

1) Particulate Filtration Efficiency (PFE)	: > 99%
2) Bacterial Filtration Efficiency (BFE)	: > 99.99%
3) Viral Filtration Efficiency (VFE)	: > 99.9a%
4) Bacterial Killing Rate	: > 99.99%
5) H3N2 Killing Rate	: > 99.99%
6) COVID-19 Killing Rate	: 99.81%
7) Differential Pressure	: < 5mmH20
8) Splash Resistance Pressure	: < 160mmHg
9) Microbial Cleanliness	: < 30cfu/g
10) Flame Spread	: < 5 Seconds
11) Shelf Life	: 5 Years
Packing Details	: 1 Carton X 20 Boxes X 30 Pieces
Carton Size	: 645mm X 310mm X 300mm
Gross Weight	: 4.9kg

KV99 Cup Mask

(3M 1860 Alternative)

Article No	: KV99-3
Product Name	: Curie Disposable Cup Shaped Respirator
Standard Applied	: NIOSH N95 / EN149 FFP2
Specification	: Cup Shaped, 10.7cm X 16cm
Material	: 34% Positive Charged Biohazard Filter 22% Meltblown Non-Woven / 44% Non-Woven Fabric

Main Performance:

1) Particulate Filtration Efficiency (PFE)	: > 99%
2) Bacterial Filtration Efficiency (BFE)	: > 99.99%
3) Viral Filtration Efficiency (VFE)	: > 99.9a%
4) Bacterial Killing Rate	: > 99.99%
5) H3N2 Killing Rate	: > 99.99%
6) COVID-19 Killing Rate	: 99.81%
7) Differential Pressure	: < 5mmH20
8) Splash Resistance Pressure	: < 160mmHg
9) Microbial Cleanliness	: < 30cfu/g
10) Flame Spread	: < 5 Seconds
11) Shelf Life	: 5 Years
Packing Details	: 1 Carton X 20 Boxes X 20 Pieces
Carton Size	: 670mm X 435mm X 320mm
Gross Weight	: 6.5kg

KV99 4-Layer Surgical Grade Respirator / Arrest + Kill

Ultra-Protection, Anti-viral & Anti-bacterial, Light & Airy, Long-Lasting

Viral Filtration Efficiency 99.9a% / Killing COVID-19 99.81%

Strong Protection

Highest medical-grade protection (PFE > 99%, VFE / BFE > 99.9a%), meeting ASTM F2101 Level 3 and EN14683 standard, for a peace-of-mind.

Antiviral & Antibacterial

Kills COVID-19 (99.81%), virus (>99.99%) and bacteria (>99.99%) in seconds, greatly reducing risk for 2nd infection.

Light & Airy

Ultra-high breathability for more comfortable mask experience, 50% more breathable vs comparable masks.

Long-Lasting

Humidity and temperature proof – Curie patented strong polycationic nanostructure maintain ultrafiltration and disinfection efficiency, it can remain BFE > 99.9a% after conditioning in 120℃ for 48 hours. Effective period more then for 5 years under optimal storage conditions.

KV99 4-Layer Surgical Grade Respirator / Arrest + Kill

Qualifications and Certifications

US Patent Number
62988900

HK Patent Number
32020008506.8

US FDA Establishment Registration and Device Listing - Registered Establishment Number
3016752122

US FDA Establishment Registration and Device Listing - Owner/Operator Number
10063209

US FDA Personal Protective Equipment Emergency Use Authorization (PPE EUA)
Authorized Imported

NIOSH N95 Respirator Approval No:
TC-84A-7228
TC-84A-6973

EU CE Disposable Medical Face Mask Class I / Type IIR - Registration Number
DE/CA05/MP-238321-2556-00
DE/CA05/MP-238321-2557-00

EU CE EN149:2001+A1:2009 - FPC Certificate No
CE-PC-200402-188-FPC-A
CE-PC-200402-188-01-9A
CE-PC-200402-188-FPC-B
CE-PC-200601-452-01-9A
CEC40159

AS/NZS 1716:2012 - Respiratory Protective Devices Licence No:
SMK40477

China Chamber of Commerce for Import and Export of Medicines and Health Products, White List of Medical Devices and Supplies Companies
- Unified Social Credit Identifier
91430181MA4PHUE510

KV99 4-Layer Surgical Grade Respirator / Arrest + Kill

Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate - ARTG Identifier

Medical Device Included Class 1

338879

337859

338878

338713

337857

ANVISA

Brazil National Health Surveillance Agency ANVISA - Registration Number

Medical Device Class 1 – 81702110005

Health Canada

Canada Medical Device Establishment Licence - Licence Number

Class 1 Manufacturer – 14507

KOTITI
Testing & Research Institute

Korea Textile Inspection & Testing Institute Registration Number

SUQ20-00040_M1

SUQ20-00041_M1

SUQ20-00042_M1

SUQ20-00043_M1

FDA
Taiwan FDA Approved

Taiwan Ministry of Health and Welfare Medical Device Manufacturing No.

008382

ISO

ISO9001:2015

Certificate No: USA20Q40924R0M

ISO 14001:2015

Certificate No: USA20E40925R0M

EN ISO 13485:2016

Certificate No: CN20/42091

Nelson Labs
A Sotera Health company

Viral Filtration Efficiency (VFE) in ASTM F2101

Proven that Curie technology can effectively filter virus (>99.9a%)

Nelson Labs
A Sotera Health company

Bacterial Filtration Efficiency with Increased Delivery Challenge (BFE) in ASTM F2101 and EN14683

Proven that Curie technology can effectively filter increased challenge of bacteria (99.8%)

KV99 4-Layer Surgical Grade Respirator / Arrest + Kill

Viral Filtration Efficiency (VFE) in ASTM F2101

Proven that Curie technology can effectively filter virus (>99.9a%)

Bacterial Filtration Efficiency (BFE) in ASTM F2101 and EN14683

Proven that Curie technology can effectively filter bacteria (99.9%), complying ASTM F2101 Level 3 and EN14683 Type IIR

Air Exchange Pressure in ASTM F2101 / EN14683

Proven that air exchange pressure of KV99 masks can comply with standards of ASTM F2101 Level 3 and EN14683 Type IIR

Microbial Cleanliness (Bioburden) of Medical Masks in EN14683

Proven that total bioburden of KV99 can comply with standard of EN14683 Type IIR (<6 cfu)

Synthetic Blood Penetration Pressure in ASTM F2101 / ASTM F1862 / EN14683

Proven that KV99 mask can effectively intercept fluid (160mmHg) from penetration, complying ASTM F2101 Level 3 and EN14683 Type IIR

Sub-Micron Particulate Filtration Efficiency (0.1μm PSL) in ASTM F2101 / ASTM F2299 / EN14683

Proven that KV99 masks can effectively filter 0.1μm sub-micron particulate (>99.8%), complying ASTM F2101 Level 3 and EN14683 Type IIR

Standard for the Flammability of Clothing Textiles - US 16 CFR Part 1610

Proven that KV99 masks can comply with Class 1 - Normal Flammability

Intertek's Tick Mark

Proven that KV99 masks were independently tested by Intertek. Safety, quality and performance of KV99 masks are endorsed by Intertek.

Determination of Antiviral Activity of Textile Products BS ISO 18184

Proven that Curie technology can effectively kill COVID-19 Coronavirus SARS-CoV-2 (>99.81%)

Sub-Micron Particulate Filtration Efficiency (0.1μm PSL) in ASTM F2101 / ASTM F2299 / EN14683

Proven that KV99 masks can effectively filter 0.1μm sub-micron particulate (>99%), complying ASTM F2101 Level 3 and EN14683 Type IIR

KV99 4-Layer Surgical Grade Respirator / Arrest + Kill

紡織產業綜合研究所
Taiwan Textile Research Institute

Air Exchange Pressure in ASTM F2101 / EN14683

Proven that air exchange pressure of KV99 masks can comply with standards of ASTM F2101 Level 3 and EN14683 Type IIR

Synthetic Blood Penetration Pressure in ASTM F2101 / ASTM F1862 / EN14683

Proven that KV99 mask can effectively intercept fluid (160mmHg) from penetration, complying ASTM F2101 Level 3 and EN14683 Type IIR

香港公開大學
THE OPEN UNIVERSITY OF HONG KONG

Bacterial Filtration Efficiency (BFE) in ASTM F2101

Proven that Curie technology can effectively filter bacteria (>99%)

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THE OPEN UNIVERSITY OF HONG KONG

Standard Guide for Accelerated Ageing of Sterile Barrier Systems for Medical Devices in ASTM F1980-16

Bacterial Filtration Efficiency (BFE) in ASTM F2101

Proven that Curie technology can effectively filter bacteria (>99%), after conditioning KV99 masks in 120°C for 48 hours, to simulate storing in room temperature for 5 years.

香港公開大學
THE OPEN UNIVERSITY OF HONG KONG

Determination of Antibacterial Activity of Textile Products BS EN ISO 20743

Proven that Curie technology can effectively kill bacteria (>99%) · In less than 60 seconds.

广东省微生物分析检测中心
Guang Dong Detection Center Of Microbiology

Determination of Antiviral Activity of Textile Products BS ISO 18184

Proven that Curie technology can effectively kill Influenza A Virus Subtype H3N2 (>99.99%)

Determination of alkylphenols (AP) of Textile Products EN ISO 21084:2019

Proven that Alkylphenols (AP) is not detected from Curie technology

BUREAU VERITAS 1828
BUREAU VERITAS

Detection and Determination of Alkylphenol Ethoxylates (APEO) of Textile Products EN ISO 18254:2016

Proven that Alkylphenol Ethoxylates (APEO) is not detected from Curie technology

Determination of Formaldehyde - Free and Hydrolysed Formaldehyde of Textile Products EN ISO 14184:2011 / JIS L 1041

Proven that Formaldehyde is not detected from Curie technology, and it reach safety level for Type 1 – Baby < 36 Months

KV99 4-Layer Surgical Grade Respirator / Arrest + Kill

Determination of Tetrachlorophenol-, Trichlorophenol-, Dichlorophenol-, Monochlorophenol-Isomers and Pentachlorophenol Content of Textile Products DIN EN ISO 17070:2015 / 64 LFBG B 82.02-08 (Modified)

Proven that Chlorophenols Content and Ortho-Phenylphenol (OPP) are not detected from Curie technology

Determination of the Phthalate Content of Textile Products EN ISO 14389: 2014 / US CPSC-CH-C1001-09.4

Proven that Phthalate Content are not detected from Curie technology

KV99 4-Layer Surgical Grade Respirator / Arrest + Kill

Curie Filtration Technology

- Curie's Filtration Technology is applicable to different materials. This viral and bacterial filtration technology is proven by multiple lab tests by renowned certification organizations;
- Curie Filtration Technology arrests and kills virus and bacteria; obtained US and Hong Kong patents;
- Wide-range of uses for combating COVID-19 pandemic: masks and other daily-use products, providing protection against viruses and bacteria;
- Curie is the first to commercialize and mass-produce this high-efficiency, cost-effective virus killing technology
- This patented technology combines the team's expertise in chemistry and applied materials, cumulating in this "World 1st" technology.

Curie Advantage

The first application of Curie's Filtration Technology is applied to PPE mask products, and has been tested and proven to arrest and kill viruses and bacteria; "Ultra-Protection, Anti-viral & Anti-bacterial, Light & Airy, Long-Lasting", KV99 is a much better mask when compared to any other masks in the market.

	Disposable (and reusable) Masks Using Curie's Ultrahigh-Efficiency Filtration Tech	Traditional Disposable Mask Using Meltblown Material
Filtration / Killing Mechanism	High efficiency: According to ASTM F2101 and EN14683 test results show: VFE > 99.9a% BFE > 99.99% The highly positive-charged fibers inside Curie's Filtration material attracts and arrests highly negative-charge protein spikes on virus and bacteria.	Meltblown cloth relies on electrostatic to capture bacteria and viruses. Surface proteins of bacteria and viruses are negative-charged, and the static electricity itself is negative. The polarity of the two is the same and therefore it repels – inefficient in capturing microbials. Electrostatic itself is unstable, and it is easy to dissipate and discharge due to high temperature and humidity. Few hours after the mask used, the filtration efficiency begins to decay.
Principles of Protection	Ultra-protection: According to the test performed by the Open University of Hong Kong, the extremely strong positive charge from the bottom layer of Curie's fibre can block virus and bacteria by tearing the outer envelope and membrane of virus and bacteria within 60 seconds. Killing Rate of COVID-19 – 99.81% Killing Rate of H3N2 > 99.99% Killing Rate of Bacteria > 99.99%	Traditional masks only act as a barrier to block bacteria or viruses from the user, but they do not have the function of killing. This means bacteria or viruses will start to multiply on the meltblown fabric fibres; therefore after few-hours of usage, the mask surface becomes infectious with bacteria and viruses, potentially causing secondary infection on whoever or whatever person or surface it comes into contact.

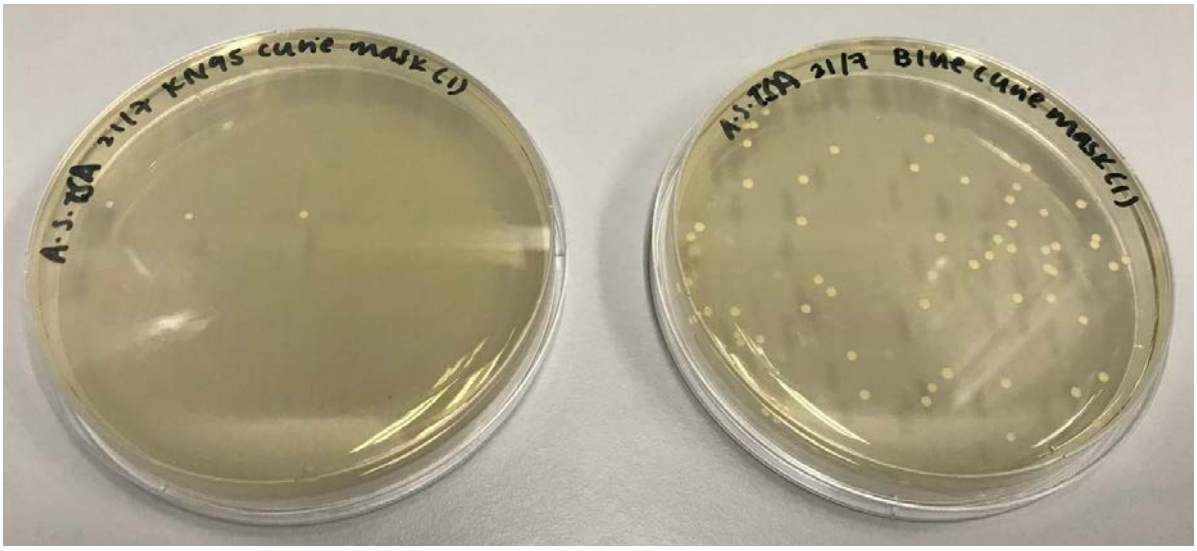
KV99 4-Layer Surgical Grade Respirator / Arrest + Kill

Effective Period	Long-lasting: Curie's Filtration Technology material was tested against storage in an environment of 120°C for 48 hours, in accordance with ASTM F1980 standard simulating 5 year storage conditions. After the test, Curie's filter materials still maintain high efficiency (BFE > 99.99%) and function. , It allows long term storage that large enterprises, governments or public institutions require.	The effective period is short, and it is most likely due to external factors in the transportation process (such as high temperature or improper storage), electrostatic loss of the meltblown is significant over-time, causing the product to be ineffective.
Air Permeability	High air permeability: Compared with traditional masks, the air resistance is reduced and the air permeability is high. Making a long period of usage more comfortable.	Most traditional masks sacrifice breathability in order to achieve the high filtration efficiency expected by users.

KV99 4-Layer Surgical Grade Respirator / Arrest + Kill

Comparison between Curie's Mask and Traditional Disposable Mask Using Meltblown

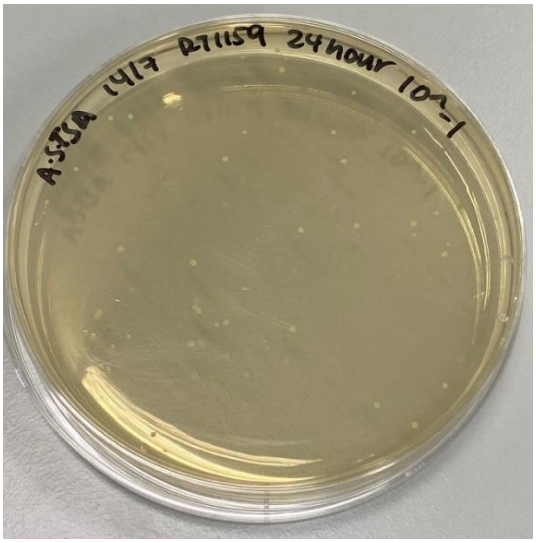
Difference on Bacterial Filtration Efficiency (BFE) after Electrostatic Discharged



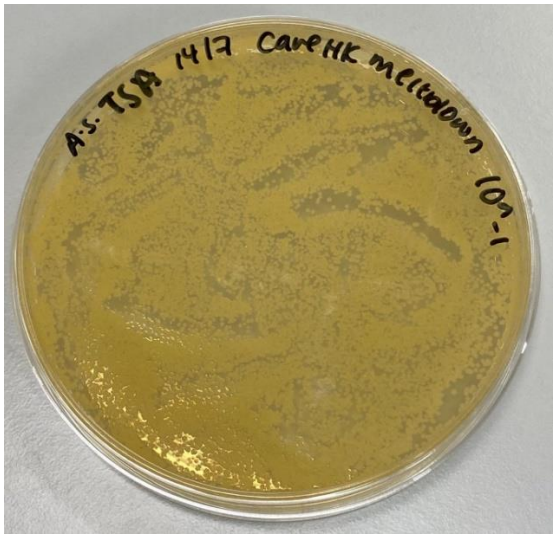
Curie's Mask
(BFE > 99%)

Traditional Disposable Mask Using Meltblown
(BFE < 90%)

Difference on Bacterial Growth after 8 Hours Use of Masks



Curie's Mask
(Killing Bacteria > 99%)



Traditional Disposable Mask Using Meltblown
(Full of Bacteria)

US Patent Number

US 62/988,900

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
62/988,900	03/12/2020		85	WIPC2002		

CONFIRMATION NO. 9401

UPDATED FILING RECEIPT

166693
Law Offices of Sergei Orel, LLC
2125 Center Avenue, Suite 616
Fort Lee, NJ 07024

OC000000118340987

Date Mailed: 07/09/2020

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

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Inventor(s)

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Chun Yin OR, Cheung Sha Wan, HONG KONG;

Applicant(s)

Jianliang GONG, Yau Ma Tei, HONG KONG;
Chun Yin OR, Cheung Sha Wan, HONG KONG;

Power of Attorney:
Michael Yablonsky--40407

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

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The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 62/988,900**
Projected Publication Date: None, application is not eligible for pre-grant publication
Non-Publication Request: No
Early Publication Request: No

** MICRO ENTITY **
Title

Air Filtration System and Manufacturing Method Therefor

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

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HK Patent Number
32020008506.8

香港特別行政區政府知識產權署專利註冊處
Patents Registry, Intellectual Property Department
The Government of the Hong Kong Special Administrative Region

知識產權署
Intellectual Property Department

In reply please quote this ref.: 32020008506.8
Your ref.: C200101/UM1HK
Tel.: 3543 1464
Fax.: 2838 6315

eMode

08 June, 2020

WORLD IP CONSULTANCY
Unit B, 3/F, Cheong Yu Bldg
No. 143-151 Castle Peak Rd, Yuen Long
HONG KONG

Application for Grant of a Short-term Patent
Under Application No. 32020008506.8

We refer to your application for a short-term patent lodged on 02 June, 2020.

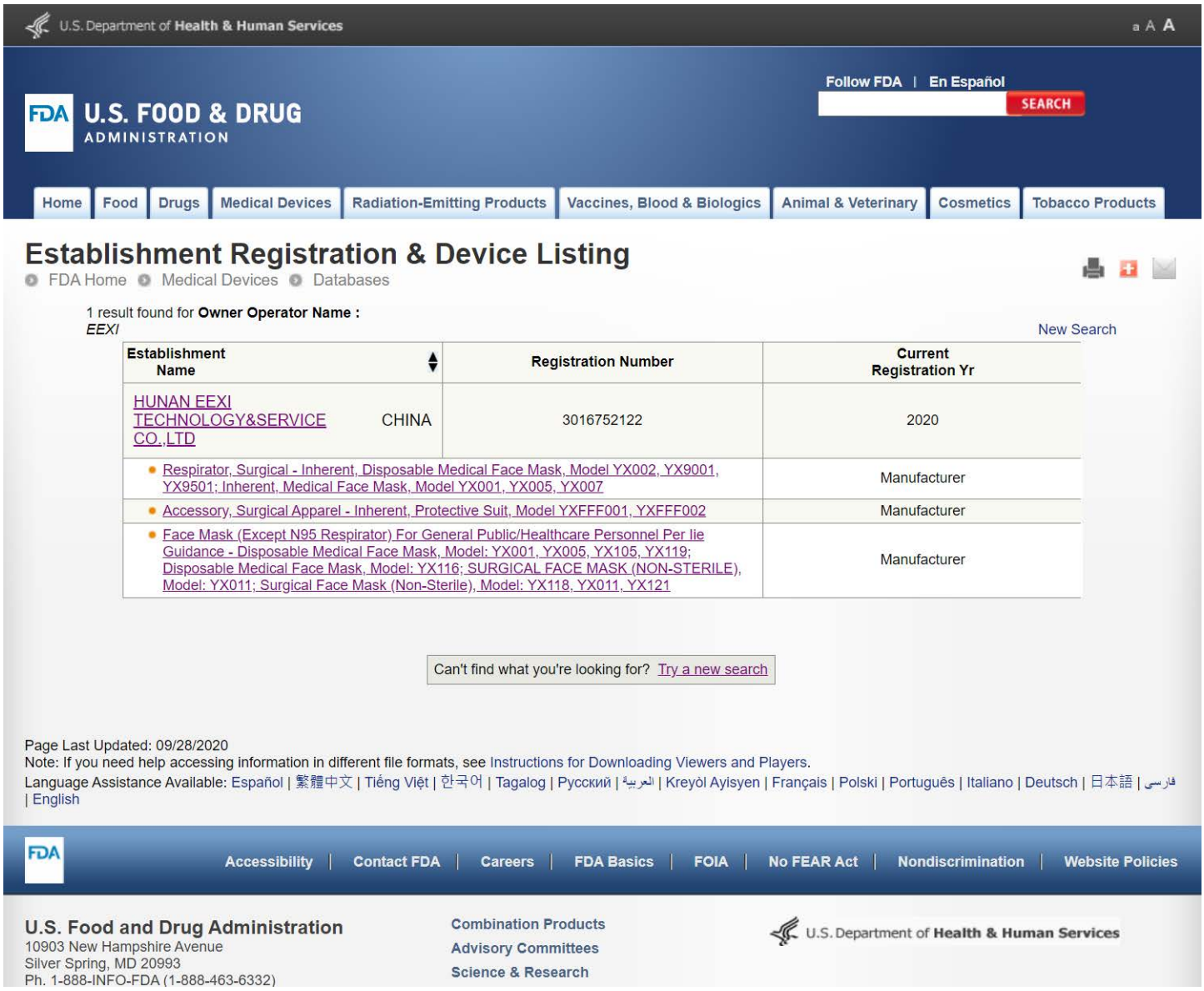
The above application is found to have satisfied the minimum requirements as laid down in section 114(2) of the Patents Ordinance. The accorded date of filing is 02 June, 2020.

In general, you will receive our further letter for the application at least five months after the date of this letter. If you do not receive any letter from us after this period, please contact us at 2961 6901.

This is a letter issued by Nigel LEE for Registrar of Patents.

(This is a computer-generated copy. No signature is required.)

US FDA Establishment Registration and Device Listing - Registered Establishment Number 3016752122



U.S. Department of Health & Human Services

a A A

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1 result found for **Owner Operator Name :**
EEXI

New Search

Establishment Name		Registration Number	Current Registration Yr
HUNAN EEXI TECHNOLOGY&SERVICE CO.,LTD	CHINA	3016752122	2020
• Respirator, Surgical - Inherent, Disposable Medical Face Mask, Model YX002, YX9001, YX9501; Inherent, Medical Face Mask, Model YX001, YX005, YX007			Manufacturer
• Accessory, Surgical Apparel - Inherent, Protective Suit, Model YXFFF001, YXFFF002			Manufacturer
• Face Mask (Except N95 Respirator) For General Public/Healthcare Personnel Per Iie Guidance - Disposable Medical Face Mask, Model: YX001, YX005, YX105, YX119; Disposable Medical Face Mask, Model: YX116; SURGICAL FACE MASK (NON-STERILE), Model: YX011; Surgical Face Mask (Non-Sterile), Model: YX118, YX011, YX121			Manufacturer

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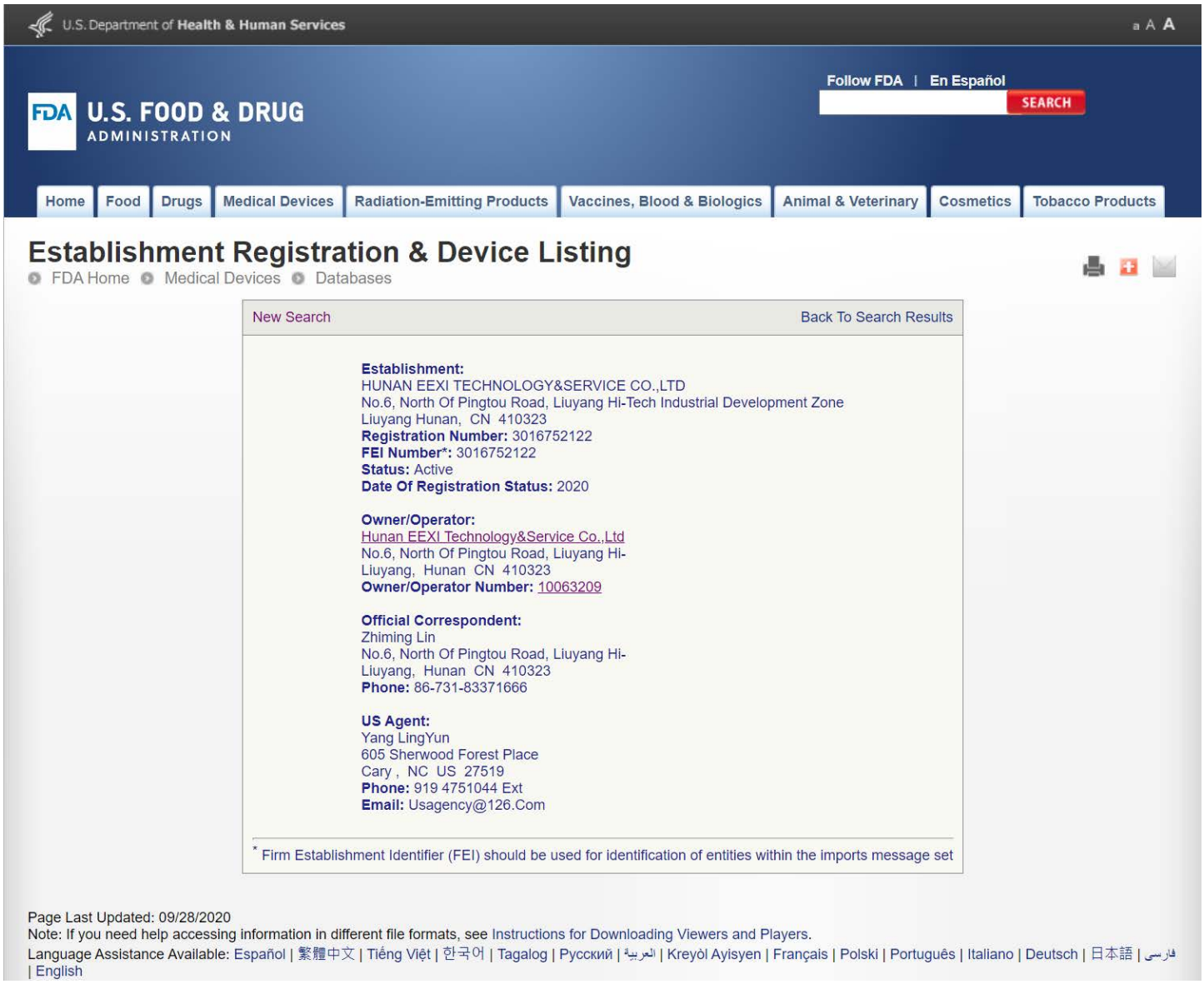
US FDA Establishment Registration and Device Listing - Owner/Operator Number

10063209



https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=240648

NIOSH N95 Respirator Approval No:

TC-84A-7228

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

December 15, 2014

NIOSH Reference: TN-19825
Mfr. Reference: GHCL-288

Mr. Wanghua Xu
Management Representative
Guangzhou Harley Commodity Company Limited
Floor 1 to 4, #8, Team 17, Sandong Village
Xinhua Street, Huadu District
Guangzhou 510800
CHINA

Dear Mr. Xu:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted September 17, 2014. This request was for approval of the model L-288 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference assembly matrix L-288 AMa.xls.

This request is granted. Approvals are granted for English language only on all documentation. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. Approval number TC-84A-7228 has been assigned. This respirator is approved for protection against particulates at a N95 filter efficiency level.

The CD enclosed with this letter contains the final respirator approval label. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely yours,

Jonathan V. Szalajda
Acting Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Technology Evaluation Branch
Certification, Evaluation and Testing Section
P.O. Box 18070
Pittsburgh, PA 15236

TEST REPORT

Task Number: TN-19825

Manufacturer: Guangzhou Harley Commodity Company Limited

Prepared by: Nichole Petitta

Tests Conducted by: Nichole Petitta

Date: November 21, 2014

Respirator Tested: L-288 N95

Background Information

Respirator tested as per test request.

Tests Assigned

Test Description	STP Number
A. Exhalation Resistance Test	RCT-APR-STP-0003
B. Inhalation Resistance Test	TEB-APR-STP-0007
C. Sodium Chloride (NACL) N95 Test	TEB-APR-STP-0059

Overall Results

The respirator system tested met the requirements of all the procedures listed above.

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-19825 **Reference No.:** CFR 84.180
Test: Exhalation Resistance Test **STP No.:** 3
Manufacturer: Guangzhou Harley Commodity Company Limited

Filter Type: Filter Only

Item Tested: L-288 N95

Sample	Maximum Allowable Resistance (MM of H2O) Exhalation	Actual Resistance (MM of H2O) Exhalation	Result
1	25	10.8	PASS
2	25	10.7	PASS
3	25	10.3	PASS

Overall Result: PASS

Comments:

Samples were tested on Brooks meter 000283.

Was all equipment verified to be in calibration throughout all testing? (•) Yes ( ) No

Signature: Nicole L. Petitta **Date:** 11/4/2014

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-19825 **Reference No.:** CFR 84.180
Test: Inhalation Resistance Test **STP No.:** 7
Manufacturer: Guangzhou Harley Commodity Company Limited
Item Tested: L-288 N95

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O) Inhalation	Actual Resistance (MM of H2O) Inhalation	Result
1	35	11.4	PASS
2	35	11.7	PASS
3	35	10.9	PASS

Overall Result: PASS

Signature: Nicole L. Petitta **Date:** 11/4/2014

Engineering Technician

Task Number: TN-19825 **Reference No.:** CFR 84.180
Test: Inhalation Resistance Test **STP No.:** 7
Manufacturer: Guangzhou Harley Commodity Company Limited
Item Tested: L-288 N95

Comments:
Samples were tested on Brooks meter 000036.

Was all equipment verified to be in calibration throughout all testing? (•) Yes ( ) No

Signature: Nicole L. Petitta **Date:** 11/4/2014

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-19825 **Reference No.:** CFR 84.181
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer: Guangzhou Harley Commodity Company Limited
Item Tested: L-288 N95

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	12.2	5.00	0.379	0.388	PASS
2	85	12.2	5.00	0.559	0.560	PASS
3	85	11.6	5.00	0.781	0.765	PASS
4	85	12.0	5.00	0.650	0.650	PASS
5	85	11.7	5.00	0.665	0.665	PASS
6	85	12.3	5.00	0.520	0.520	PASS
7	85	10.9	5.00	0.598	0.598	PASS
8	85	12.5	5.00	1.390	1.490	PASS
9	85	11.3	5.00	0.794	0.794	PASS
10	85	13.2	5.00	0.654	0.654	PASS
11	85	13.3	5.00	0.610	0.610	PASS
12	85	11.4	5.00	0.629	0.629	PASS
13	85	12.1	5.00	0.640	0.640	PASS
14	85	12.0	5.00	0.755	0.755	PASS
15	85	11.7	5.00	0.899	0.934	PASS
16	85	12.2	5.00	0.616	0.616	PASS
17	85	12.0	5.00	0.684	0.684	PASS
18	85	12.7	5.00	0.501	0.501	PASS
19	85	11.0	5.00	0.319	0.326	PASS
20	85	11.4	5.00	0.669	0.669	PASS

Overall Result: PASS

Signature: Nicole L. Petitta **Date:** 11/21/2014

Engineering Technician

Task Number: TN-19825 **Reference No.:** CFR 84.181
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer: Guangzhou Harley Commodity Company Limited
Item Tested: L-288 N95

Comments:

Samples were tested on TSI 8130 machine 000192 with samples 1-3 using timer 000214.

Was all equipment verified to be in calibration throughout all testing? (•) Yes ( ) No

Signature: Nicole L. Petitta **Date:** 11/21/2014

Engineering Technician

NIOSH N95 Respirator Approval No:

TC-84A-7228

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

December 15, 2014

NIOSH Reference: TN-19824
Mfr. Reference: GHCL-188

Mr. Wanghua Xu
Management Representative
Guangzhou Harley Commodity Company Limited
Floor 1 to 4, #8, Team 17, Sandong Village
Xinhua Street, Huadu District
Guangzhou 510800
CHINA

Dear Mr. Xu:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted September 17, 2014. This request was for approval of the model L-188 N95 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference assembly matrix L-188 Ama.xls. In addition, the Guangzhou Harley Commodity Company QA Manual, version A1, effective date 2014-06-10, was submitted for review.

This request is granted. Approvals are granted for English language only on all documentation. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. Approval number TC-84A-6973 has been assigned. This respirator is approved for protection against particulates at a N95 filter efficiency level.

NIOSH has also reviewed the quality manual presented and finds that this manual meets or exceeds the minimum technical requirements for quality assurance plans as outlined in Title 42, *Code of Federal Regulations* (CFR), Part 84.41(a) and, on the basis of this review, this quality manual is accepted.

The CD enclosed with this letter contains the final respirator label. The abbreviated label is accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

A copy of the quality manual will be retained by NIOSH and incorporated into our files. Any future changes to this accepted quality document must be submitted to NIOSH for a modification of this accepted quality system.

Sincerely yours,

Jonathan V. Szalajda
Acting Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Technology Evaluation Branch
Certification, Evaluation and Testing Section
P.O. Box 18070
Pittsburgh, PA 15236

TEST REPORT

Task Number: TN-19824

Manufacturer: Guangzhou Harley Commodity Company Limited

Prepared by: Nichole Petitta

Tests Conducted by: Nichole Petitta

Date: November 13, 2014

Respirator Tested: L-188 N95

Background Information

Respirator tested as per test request.

Tests Assigned

Test Description	STP Number
A. Exhalation Resistance Test	RCT-APR-STP-0003
B. Inhalation Resistance Test	TEB-APR-STP-0007
C. Sodium Chloride (NACL) N95 Test	TEB-APR-STP-0059

Overall Results

The respirator system tested met the requirements of all the procedures listed above.

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-19824 **Reference No.:** CFR 84.180
Test: Exhalation Resistance Test **STP No.:** 3
Manufacturer: Guangzhou Harley Commodity Company Limited

Filter Type: Filter Only

Item Tested: L-188 N95

Sample	Maximum Allowable Resistance (MM of H2O) Exhalation	Actual Resistance (MM of H2O) Exhalation	Result
1	25	9.6	PASS
2	25	8.9	PASS
3	25	8.5	PASS

Overall Result: PASS

Comments:

Samples were tested on Brooks meter 0000283.

Was all equipment verified to be in calibration throughout all testing? (•) Yes ( ) No

Signature: Nicole L. Petitta **Date:** 11/4/2014

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-19824 **Reference No.:** CFR 84.180
Test: Inhalation Resistance Test **STP No.:** 7
Manufacturer: Guangzhou Harley Commodity Company Limited
Item Tested: L-188 N95

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O) Inhalation	Actual Resistance (MM of H2O) Inhalation	Result
1	35	10.5	PASS
2	35	10.5	PASS
3	35	9.7	PASS

Overall Result: PASS

Signature: Nicole L. Petitta **Date:** 11/4/2014

Engineering Technician

Task Number: TN-19824 **Reference No.:** CFR 84.180
Test: Inhalation Resistance Test **STP No.:** 7
Manufacturer: Guangzhou Harley Commodity Company Limited
Item Tested: L-188 N95

Comments:
Samples were tested on Brooks meter 000036.

Was all equipment verified to be in calibration throughout all testing? (•) Yes ( ) No

Signature: Nicole L. Petitta **Date:** 11/4/2014

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-19824 **Reference No.:** CFR 84.181
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer: Guangzhou Harley Commodity Company Limited
Item Tested: L-188 N95

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	9.6	5.00	0.517	0.517	PASS
2	85	10.6	5.00	0.694	0.694	PASS
3	85	9.8	5.00	0.718	0.718	PASS
4	85	10.3	5.00	0.651	0.654	PASS
5	85	9.3	5.00	0.682	0.682	PASS
6	85	9.7	5.00	0.755	0.755	PASS
7	85	10.7	5.00	0.621	0.621	PASS
8	85	9.9	5.00	0.744	0.744	PASS
9	85	9.8	5.00	0.535	0.535	PASS
10	85	10.8	5.00	1.500	1.580	PASS
11	85	10.5	5.00	0.688	0.688	PASS
12	85	9.7	5.00	0.692	0.692	PASS
13	85	10.6	5.00	0.757	0.757	PASS
14	85	10.8	5.00	0.671	0.671	PASS
15	85	10.8	5.00	0.981	0.981	PASS
16	85	10.3	5.00	0.678	0.678	PASS
17	85	9.8	5.00	0.661	0.661	PASS
18	85	10.3	5.00	0.680	0.680	PASS
19	85	9.6	5.00	1.660	1.660	PASS
20	85	9.8	5.00	0.769	0.769	PASS

Overall Result: PASS

Signature: Nicole L. Petitta **Date:** 11/13/2014

Engineering Technician

Task Number: TN-19824 **Reference No.:** CFR 84.181
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer: Guangzhou Harley Commodity Company Limited
Item Tested: L-188 N95

Comments:

All samoles were tested on TSI 8130 machine 000192 with samples 1-3 using timer 000214.

Was all equipment verified to be in calibration throughout all testing? (•) Yes ( ) No

Signature: Nicole L. Petitta **Date:** 11/13/2014

Engineering Technician

US FDA Personal Protective Equipment Emergency Use Authorization (PPE EUA)

Authorized Imported

Appendix A: Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China (Updated: September 28, 2020)

The table below includes a list of non-NIOSH respirators authorized by this Umbrella EUA for emergency use during the COVID-19 public health emergency.

As stated in the EUA, authorized respirators should be used in accordance with CDC's recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for Optimizing the Supply of N95 Respirators.

Search: EEXI

Show 100 entries

Manufacturer	Respirator Model(s)	Instructions for Use
Hunan EEXI Technology & Service Co., Ltd.	YX152, YX153	

Showing 1 to 1 of 1 entries (filtered from 166 total entries)

Previous 1 Next

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas

EU CE Disposable Medical Face Mask Class I / Type IIR - Registration Number

DE/CA05/MP-238321-2556-00

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00301588

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA05**		
	Bezeichnung / Name **Behörde für Gesundheit und Verbraucherschutz, Referat V43**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20539**
	Straße, Haus-Nr. / Street, house no. **Billstraße 80**		
	Telefon / Phone **+49-40-428280**		Telefax / Fax **+49-40-427310017**
	E-Mail / E-mail **medizinprodukte@bgv.hamburg.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **09.04.2020**		Registriernummer / Registration number **DE/CA05/MP-238321-2556-00**
	Typ der Anzeige / Notification type ☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change ☐ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG ☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV ☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

EC Declaration of Conformity

Manufacturer: Hunan EEXI Technology&Service Co.,Ltd.

Address: No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China

EU Authorised Representative:
Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Device Name: Disposable medical face mask

Type: Type I

Classification : Class I
According to 93/42/EEC Annex IX, Rules 1, all non-invasive devices are in Class I, unless one of the rules set out hereinafter applies. The Conformity Route is Annex VII EC declaration of conformity.

We, Hunan EEXI Technology&Service Co.,Ltd. herewith declare on our exclusive responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC and 2007/47/EC for medical devices as transposed into national law. All supporting documentation is retained under the premises of the manufacturer.

The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product.

Harmonized Standards:

All applicable harmonized Standards (Published in the Official Journal of the European Communities)
Please see Annex List.

Date of Issue:

10th May 2020

Signature:

Robbin Liu

General Manager

EU CE Disposable Medical Face Mask Class I / Type IIR - Registration Number

DE/CA05/MP-238321-2557-00

Anlage 1
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00300695

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika
Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA05**		
	Bezeichnung / Name **Behörde für Gesundheit und Verbraucherschutz, Referat V43**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20539**
	Straße, Haus-Nr. / Street, house no. **Billstraße 80**		
	Telefon / Phone **+49-40-428280**		Telefax / Fax **+49-40-427310017**
	E-Mail / E-mail **medizinprodukte@bgv.hamburg.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **09.04.2020**		Registriernummer / Registration number **DE/CA05/MP-238321-2557-00**
	Typ der Anzeige / Notification type ☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change ☐ Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG ☐ Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV ☐ Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

EC Declaration of Conformity

Manufacturer: Hunan EEXI Technology&Service Co.,Ltd.

Address: No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan, China

EU Authorised Representative:
Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Device Name: Disposable Surgical mask

Type: Type IIR

Classification : Class I
According to 93/42/EEC Annex IX, Rules 1, all non-invasive devices are in Class I, unless one of the rules set out hereinafter applies. The Conformity Route is Annex VII EC declaration of conformity.

We, Hunan EEXI Technology&Service Co.,Ltd. herewith declare on our exclusive responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC and 2007/47/EC for medical devices as transposed into national law. All supporting documentation is retained under the premises of the manufacturer.

The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product.

Harmonized Standards:

All applicable harmonized Standards (Published in the Official Journal of the European Communities)
Please see Annex List.

Date of Issue:

10th May 2020

Signature:

Robbin Liu

General Manager

EU CE EN149:2001+A1:2009 – FFP2 FPC Certificate No

CE-PC-200402-188-FPC-A

Certificate of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

FPC Certificate No.: CE-PC-200402-188-FPC-A

Certificate holder:	**Hunan EEXI Technology & Service Co., Ltd.** No.6, North of Pingtou Road, Liuyang Hi-Tech Industrial Development Zone, Hunan, China
The scope of the certification for:	**Respiratory Protective Equipment** Products covered by the certificate are described below.
Model:	Particle Filtering Half Mask YX009
Standard:	EN 149:2001+A1:2009
Validity from:	2020-05-29
To:	2020-08-28

CCQS Certification Services Limited in its role as a Notified Body for PPE Regulation, is monitoring that the manufacturer is producing PPE in conformity with the type described in the EU type-examination certificate and associated technical file and which satisfies the Essential Health and Safety Requirements of the Regulation.
The manufacturer is hereby authorized to affix our Notified Body number, 2834, to each item of PPE as identified on this certificate whilst this certificate remains valid.
This certificate is the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.

CE

Approved by Ireland Government as a Notified Body for CE Marking No.2834

ISO 17065 IVNAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG NO.6012R

Approved by:

CCQS Ireland Certification

Owen Bian, Director

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

EU CE EN149:2001+A1:2009 – FFP2 NR, FPC Certificate No

CE-PC-200402-188-01-9A

Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200402-188-01-9A

Certificate holder:	**Hunan EEXI Technology & Service Co., Ltd.** No.6, North of Pingtou Road, Liuyang Hi-Tech Industrial Development Zone, Hunan, China
Product:	**Particle Filtering Half Mask** Folding filtering half mask without valve fitted with ear loops with head harness clip, external metal nose clip Classification: FFP2 NR
Model reference:	YX009
Standard(s):	EN 149:2001+A1:2009
Test report No.:	2020(D) - 0179
Issue date:	2020-05-29
Expiry date:	2020-08-28

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425 and meeting the needs of WHO document dcp-ncov.pdf and EU Commission Recommendation (EU) 2020/403.
Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS Certification Services Limited for review.
CE marking shall not be applied until the requirements of all the PPE Regulation 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.
If the certified product is Category III then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.
This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.

CE

Approved by Ireland Government as a Notified Body for CE Marking No.2834

IVNAB ISO 17065 ACCREDITED PRODUCT CERTIFICATION

Approved by:

CCQS Ireland Certification

Owen Bian, Director

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

EU CE EN149:2001+A1:2009 – FFP2 NR, FPC Certificate No

CE-PC-200402-188-FPC-B

Certificate of Module C2 production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

FPC Certificate No.: CE-PC-200402-188-FPC-B

Certificate holder:	**Hunan EEXI Technology & Service Co., Ltd.** No.6, North of Pingtou Road, Liuyang Hi-Tech Industrial Development Zone, Hunan, China
The scope of the certification for:	**Respiratory Protective Equipment** Products covered by the certificate are described below
Model:	Particle Filtering Half Mask YX009, YX135
Standard:	EN 149:2001+A1:2009
Validity from:	2020-05-29
Revision date	2020-06-19
To:	2020-08-28

CCQS Certification Services Limited in its role as a Notified Body for PPE Regulation, is monitoring that the manufacturer is producing PPE in conformity with the type described in the EU type-examination certificate and associated technical file and which satisfies the Essential Health and Safety Requirements of the Regulation.
The manufacturer is hereby authorized to affix our Notified Body number, 2834, to each item of PPE as identified on this certificate whilst this certificate remains valid.
This certificate is the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.

CE

Approved by Ireland Government as a Notified Body for CE Marking No.2834

ISO 17065 INAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG.NO.6028

Approved by:

CCQS Ireland Certification

Owen Bian, Director

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie
If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.

CE-PC-200601-452-01-9A

Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200601-452-01-9A

Certificate holder:	**Hunan EEXI Technology & Service Co., Ltd.** No.6, North of Pingtou Road, Liuyang Hi-Tech Industrial Development Zone, Hunan, China
Product:	**Particle Filtering Half Mask** Folding filtering half mask without valve fitted with ear loops with head harness clip, internal metal nose clip Classification: FFP2 NR
Model reference:	YX135
Standard(s):	EN 149:2001+A1:2009
Test report No.:	2020(F) - 0033
Issue date:	2020-06-19
Expiry date:	2020-09-18

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the Essential Health and Safety Requirements in Annex II of the PPE regulation 2016/425 and meeting the needs of WHO document dcp-ncov.pdf and EU Commission Recommendation (EU) 2020/403.
Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS Certification Services Limited for review.
CE marking shall not be applied until the requirements of all the PPE Regulation 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.
If the certified product is Category III then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.
This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the PPE Regulation 2016/425.

CE

Approved by Ireland Government as a Notified Body for CE Marking No.2834

ISO 17065 INAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG NO.6028

Approved by:

CCQS Ireland Certification

Owen Bian - Director

CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland
Tel: +00 353 1 588 6920 Website: www.ccqs.co.uk E-mail: info@ccqs.ie

EC TYPE EXAMINATION CERTIFICATE

SAI Global Assurance Services Limited ("SAI Global") (Notified Body No: **NB2056**) has examined the product and the related technical documentation as presented and certifies that the product complies with the Directive(s) and Standard or Specification as below and on the appendixes included with the certificate.

Certificate holder: **Guangzhou Harley Commodity Co., Ltd.**
Floor 1 to 4, #8, Team 17, Sandong Village, Xinhua Street,
Huadu District, Guangzhou, Guangdong,
P.R. China

Product Description: **Personal Protective Equipment (Category III)**
Respiratory Protective Devices

Examined for compliance with: **Directive PPE 89/686/EEC - (Article 10)**

Relevant Standard(s)/Technical Specification.
EN 149: 2001+A1:2009 - Filtering half masks to protect against particles

Original certification date: **17th Nov, 2015**

Date of issue: **17th Nov, 2015** Expiry date: **16th Nov, 2020**

Certificate No: **CEC40159**

Heather Mahon
Acting Head of Policy, Risk & Certification
Authorized Signatory

APPENDIX 1

SAI Global Assurance Services Limited ("SAI Global") (Notified Body No: NB2056) has examined the product and the related technical documentation as presented and certifies that the product complies with the Directive(s) and Standard or Specification as below.

Product Description: **Respiratory Protective Devices (Category III)**

Series	Model	Description
L-210 series	L-210	Disposable particle half mask FFP1 NR, cup shaped, adjustable noseclip (polypropylene with iron type), velvet nose pad, two elastic headbands, non-valved
	L-210C	Disposable particle half mask FFP1 NR, with active carbon layer, cup shaped, adjustable noseclip (polypropylene with iron type), velvet nose pad, two elastic headbands, non-valved
	L-210V	Disposable particle half mask FFP1 NR, cup shaped, adjustable noseclip (polypropylene with iron type), velvet nose pad, two elastic headbands, valved with silicone flap
	L-210VC	Disposable particle half mask FFP1 NR, with active carbon layer, cup shaped, adjustable noseclip (polypropylene with iron type), velvet nose pad, two elastic headbands, valved with silicone flap
L-220 series	L-220	Disposable particle half mask FFP2 NR, cup shaped, adjustable noseclip (polypropylene with iron type), velvet nose pad, two elastic headbands, non-valved
	L-220C	Disposable particle half mask FFP2 NR, with active carbon layer, cup shaped, adjustable noseclip (polypropylene with iron type), velvet nose pad, two elastic headbands, non-valved
	L-220V	Disposable particle half mask FFP2 NR, cup shaped, adjustable noseclip (polypropylene with iron type), velvet nose pad, two elastic headbands, valved with silicone flap
	L-220VC	Disposable particle half mask FFP2 NR, with active carbon layer, cup shaped, adjustable noseclip (polypropylene with iron type), velvet nose pad, two elastic headbands, valved with silicone flap
L-201 series	L-201	Disposable particle half mask FFP1 NR, cup shaped, adjustable Aluminum noseclip, soft nosefoam, two elastic headbands, non-valved
	L-201C	Disposable particle half mask FFP1 NR, with active carbon layer, cup shaped, adjustable Aluminum noseclip, soft nosefoam, two elastic headbands, non-valved
	L-201V	Disposable particle half mask FFP1 NR, cup shaped, adjustable Aluminum noseclip, soft nosefoam, two elastic headbands, valved with silicone flap
	L-201VC	Disposable particle half mask FFP1 NR, with active carbon layer, cup shaped, adjustable Aluminum noseclip, soft nosefoam, two elastic headbands, valved with silicone flap

APPENDIX 1 (CONT.)

Series	Model	Description
L-202 series	L-202	Disposable particle half mask FFP2 NR, cup shaped, adjustable Aluminum noseclip, soft nosefoam, two elastic headbands, non-valved
	L-202C	Disposable particle half mask FFP2 NR, with active carbon layer, cup shaped, adjustable Aluminum noseclip, soft nosefoam, two elastic headbands, non-valved
	L-202V	Disposable particle half mask FFP2 NR, cup shaped, adjustable Aluminum noseclip, soft nosefoam, two elastic headbands, valved with silicone flap
	L-202VC	Disposable particle half mask FFP2 NR, with active carbon layer, cup shaped, adjustable Aluminum nose clip, soft nosefoam, two elastic headbands, valved with silicone flap
L-203 series	L-203V	Disposable particle half mask FFP3 NR, cup shaped, adjustable nose clip, seal velvet, two elastic headbands with buckle, valved with silicone flap

Examined for compliance with: **Directive PPE 89/686/EEC (Article 10)**

Relevant Standard(s)/Technical Specification:
EN 149: 2001+A1:2009 - Filtering half masks to protect against particles

Technical file Reference No: **CEC40159 – CR26399**

Original date of issue: **17th Nov, 2015**

Date of issue: **17th Nov, 2015**

Certificate No: **CEC40159A1**

Heather Mahon
Acting Head of Policy, Risk & Certification
Authorized Signatory

ARTICLE 11B Directive PPE 89/686/EEC CERTIFICATE

SAI Global Assurance Services Limited ("SAI Global") (Notified Body No: **NB2056**) confirm that the Management System of **Guangzhou Harley Commodity Co., Ltd.** compiles with the requirements of Article 11b of the Directive PPE 89/686/EEC.

Certificate holder: **Guangzhou Harley Commodity Co., Ltd.**

Scope: **Manufacturing processes - Personal Protective Equipment: Respiratory Protective Devices**

Relevant Standards:
EN 149: 2001+A1:2009 - Filtering half masks to protect against particles

Manufacturing sites/facilities covered by this certificate are:
Guangzhou Harley Commodity Co., Ltd.
Floor 1 to 4, #8, Team 17, Sandong Village, Xinhua Street,
Huadu District, Guangzhou, Guangdong,
P.R. China

Technical file Reference No: **CEC40159 – CR26399**

Original certification date: **17th Nov, 2015**

Date of issue: **17th Nov, 2015** Expiry date: **16th Nov, 2020**

Certificate No: **CEC40159/11b**

Heather Mahon
Acting Head of Policy, Risk & Certification
Authorized Signatory

AS/NZS 1716:2012 - Respiratory Protective Devices Licence No:
SMK40477

STANDARDSMARK
LICENCE

SAI GLOBAL
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SCHEDULE TO
STANDARDSMARK LICENCE

SAI Global hereby grants:

Guangzhou Harley Commodity Co., Ltd.

Floor 1 to 4, #8, Team 17, Sandong Village, Xinhua Street,Huadu District, Guangzhou, Guangdong China

StandardsMark Licence

Manufactured to:

AS/NZS 1716:2012 - Respiratory protective devices

Model identification of the goods on which the STANDARDSMARK may be used:

Model ID.	Face Piece / Head Covering Type	Filter or Cartridge Type/Class	Filter or Cartridge Model Number	Facepiece/Head covering Description	Model Name (Face Piece / Head Covering)	Size Facepiece/Head covering	Facepiece/Headcovering-filtration type	Accessories or Comments	Date Endorsed
L-201	Half(1/2) facepiece-Disposable	P1	L-201	Cup shaped, adjustable Aluminum noseclip, soft nosefoam, two elastic headbands, non-valved			Filter/Cartridge(Work) Particle		6 Nov 2015
L-201C	Half(1/2) facepiece-Disposable	P1	L-201C	Cup shaped, with active carbon layer, adjustable Aluminum nose clip, soft nosefoam, two elastic headbands, non-valved			Filter/Cartridge(Work) Particle		6 Nov 2015
L-201V	Half(1/2) facepiece-Disposable	P1	L-201V	Cup shaped, adjustable Aluminum nose clip, soft nose foam, two elastic headbands, valved with silicone flap			Filter/Cartridge(Work) Particle		6 Nov 2015

Licence No: SMK40477 **Issued Date:** 9 November 2015

This schedule supersedes all previously issued schedules

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* For details of manufacture, refer to the licensee

SCHEDULE TO
STANDARDSMARK LICENCE

Model ID.	Face Piece / Head Covering Type	Filter or Cartridge Type/Class	Filter or Cartridge Model Number	Facepiece/Head covering Description	Model Name (Face Piece / Head Covering)	Size Facepiece/Head covering	Facepiece/Headcovering-filtration type	Accessories or Comments	Date Endorsed
L-201VC	Half(1/2) facepiece-Disposable	P1	L-201VC	Cup shaped, with active carbon layer, adjustable Aluminum nose clip, soft nose foam, two elastic headbands, valved with silicone flap			Filter/Cartridge(Work) Particle		6 Nov 2015
L-202	Half(1/2) facepiece-Disposable	P2	L-202	Cup shaped, adjustable Aluminum nose clip, soft nose foam, two elastic headbands, non-valved			Filter/Cartridge(Work) Particle		6 Nov 2015
L-202C	Half(1/2) facepiece-Disposable	P2	L-202C	Cup shaped, with active carbon layer, adjustable Aluminum nose clip, soft nose foam, two elastic headbands, non-valved			Filter/Cartridge(Work) Particle		6 Nov 2015
L-202V	Half(1/2) facepiece-Disposable	P2	L-202V	Cup shaped, adjustable Aluminum nose clip, soft nose foam, two elastic headbands, valved with silicone flap			Filter/Cartridge(Work) Particle		6 Nov 2015
L-202VC	Half(1/2) facepiece-Disposable	P2	L-202VC	Cup shaped, with active carbon layer, adjustable Aluminum nose clip, soft nose foam, two elastic headbands, valved with silicone flap			Filter/Cartridge(Work) Particle		6 Nov 2015

Licence No: SMK40477 **Issued Date:** 9 November 2015

This schedule supersedes all previously issued schedules

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* For details of manufacture, refer to the licensee

SCHEDULE TO
STANDARDSMARK LICENCE

Model ID.	Face Piece / Head Covering Type	Filter or Cartridge Type/Class	Filter or Cartridge Model Number	Facepiece/Head covering Description	Model Name (Face Piece / Head Covering)	Size Facepiece/Head covering	Facepiece/Headcovering-filtration type	Accessories or Comments	Date Endorsed
L-210	Half(1/2) facepiece-Disposable	P1	L-210	Cup shaped, adjustable nose clip (polypropylene with iron type), velvet nose pad, two elastic headbands, non-valved			Filter/Cartridge(Work) Particle		6 Nov 2015
L-210C	Half(1/2) facepiece-Disposable	P1	L-210C	Cup shaped, with active carbon layer, adjustable nose clip (polypropylene with iron type), velvet nose pad, two elastic headbands, non-valved			Filter/Cartridge(Work) Particle		6 Nov 2015
L-210V	Half(1/2) facepiece-Disposable	P1	L-210V	Cup shaped, adjustable nose clip (polypropylene with iron type), velvet nose pad, two elastic headbands, valved with silicone flap			Filter/Cartridge(Work) Particle		6 Nov 2015
L-210VC	Half(1/2) facepiece-Disposable	P1	L-210VC	Cup shaped, with active carbon layer, adjustable nose clip (polypropylene with iron type), velvet nose pad, two elastic headbands, valved with silicone flap			Filter/Cartridge(Work) Particle		6 Nov 2015

Licence No: SMK40477 **Issued Date:** 9 November 2015

This schedule supersedes all previously issued schedules

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* For details of manufacture, refer to the licensee

SCHEDULE TO
STANDARDSMARK LICENCE

Model ID.	Face Piece / Head Covering Type	Filter or Cartridge Type/Class	Filter or Cartridge Model Number	Facepiece/Head covering Description	Model Name (Face Piece / Head Covering)	Size Facepiece/Head covering	Facepiece/Headcovering-filtration type	Accessories or Comments	Date Endorsed
L-220	Half(1/2) facepiece-Disposable	P2	L-220	Cup shaped, adjustable nose clip (polypropylene with iron type), velvet nose pad, two elastic headbands, non-valved			Filter/Cartridge(Work) Particle		6 Nov 2015
L-220C	Half(1/2) facepiece-Disposable	P2	L-220C	Cup shaped, with active carbon layer, adjustable nose clip (polypropylene with iron type), velvet nose pad, two elastic headbands, non-valved			Filter/Cartridge(Work) Particle		6 Nov 2015
L-220V	Half(1/2) facepiece-Disposable	P2	L-220V	Cup shaped, adjustable nose clip (polypropylene with iron type), velvet nose pad, two elastic headbands, valved with silicone flap			Filter/Cartridge(Work) Particle		6 Nov 2015
L-220VC	Half(1/2) facepiece-Disposable	P2	L-220VC	Cup shaped, with active carbon layer, adjustable nose clip (polypropylene with iron type), velvet nose pad, two elastic headbands, valved with silicone flap			Filter/Cartridge(Work) Particle		6 Nov 2015

End of Record

Licence No: SMK40477 **Issued Date:** 9 November 2015

This schedule supersedes all previously issued schedules

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* For details of manufacture, refer to the licensee

SCHEDULE TO
STANDARDSMARK LICENCE

Licence No: SMK40477 **Issued Date:** 9 November 2015

This schedule supersedes all previously issued schedules

SAI GLOBAL
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* For details of manufacture, refer to the licensee

China Chamber of Commerce for Import and Export of Medicines and Health Products, White List of Medical Devices and Supplies Companies

- Unified Social Credit Identifier

91430181MA4PHUE510

不安全 | www.cccmhpie.org.cn/Pub/6325/176241.shtml

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136	一顶湖北防护用品有限公司 One Top Protective Products Co., Ltd.	91429004316478369N	欧盟CE
137	常德葛澜医疗器械有限公司 Changde Gelan Medical Device Co.Ltd	91430700352838800T	欧盟CE
138	湖南佳龙医疗器械有限公司 Hunan Jialong Medical Equipment Co., Ltd	91431103MA4R4BF30T	欧盟CE
139	湖南特瑞精密医疗器械有限公司 Hunan Triplex Precision Medical Devices Co.,Ltd.	91430105MA4L3XD298	欧盟CE
140	湖南一喜科技服务有限公司 Hunan EEXI Technology&Service Co.,Ltd.	91430181MA4PHUE510	欧盟CE
141	湖南尤米服饰有限公司 Hunan Youmi Clothing Co., Ltd	91430181MA4LY6RKOY	欧盟CE
142	常州美康纸塑制品有限公司 BH Medical Products Co., Ltd	91320400750008239J	澳大利亚TGA
143	常州美康纸塑制品有限公司 BH Medical Products Co., Ltd	91320400750008239J	美国FDA
144	江西龙腾生物高科技有限公司 Jiangxi Longteng Biological High-Tech Co. Ltd	91360400741964050T	欧盟CE
145	江西美宝利医用敷料有限公司	91360426716524387R	欧盟CE

140	湖南一喜科技服务有限公司 Hunan EEXI Technology&Service Co.,Ltd.	91430181MA4PHUE510	欧盟CE

Australian Register of Therapeutic Goods Certificate - ARTG Identifier

Medical Device Included Class 1

338879

Australian Government

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Auscanny Pty Ltd

for approval to supply

Auscanny Pty Ltd - Airway protection face mask

ARTG Identifier	338879
ARTG Start Date	3/07/2020
Product Category	Medical Device Included Class 1
GMDN	18094
GMDN Term	Airway protection face mask
Intended Purpose	Product Name: Particle filtering half mask Type: Folding filtering half mask without valve fitted with ear loops with head harness clip, internal metal nose clip. Intended Use: Single-use, disposable device, non-sterile, intended to be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations.

Manufacturer Details	Address	Certificate number(s)
Hunan EEXI Technology & Service Co Ltd	No 6 North of Pingtou Road Liuyang Hi-tech Industrial Development Zone , Hunan , China	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
  - Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Airway protection face mask

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 338879
ARTG Start Date: 3/07/2020

Australian Register of Therapeutic Goods Certificate - ARTG Identifier

Medical Device Included Class 1

337859

Australian Government

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Auscanny Pty Ltd

for approval to supply

Auscanny Pty Ltd - Airway protection face mask

ARTG Identifier	337859
ARTG Start Date	15/06/2020
Product Category	Medical Device Included Class 1
GMDN	18094
GMDN Term	Airway protection face mask
Intended Purpose	Single-use, disposable device, non-sterile, intended to be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. This mask is made of blank mask, nose piece and tie-on belt. The blank mask is made of three layers. The inner and outer layer are non-woven fabric, the middle layer is Melt-blown polypropylene.

Manufacturer Details	Address	Certificate number(s)
Hunan EEXI Technology & Service Co Ltd	No 6 North of Pingtou Road Liuyang Hi-tech Industrial Development Zone , Hunan , China	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
  - Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Airway protection face mask

Product Specific Conditions

No specific conditions have been recorded against this entry.

Australian Register of Therapeutic Goods Certificate - ARTG Identifier

Medical Device Included Class 1

338878

Australian Government

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Auscanny Pty Ltd

for approval to supply

Auscanny Pty Ltd - Airway protection face mask

ARTG Identifier	338878
ARTG Start Date	3/07/2020
Product Category	Medical Device Included Class 1
GMDN	18094
GMDN Term	Airway protection face mask
Intended Purpose	Product Name: Disposable medical face mask Type and Specification: Flat earloop, 14.5×9cm. Intended Use: Single-use, disposable device, non-sterile, intended to be used for children to reduce the risk of spread of infections particularly in epidemic or pandemic situations Structure and Components: This mask is made of blank mask, nose piece and ear loops. The blank mask is made of three layers. The inner and outer layers are non-woven fabric, the middle layer is melt-blown polypropylene.

Manufacturer Details	Address	Certificate number(s)
Hunan EEXI Technology & Service Co Ltd	No 6 North of Pingtou Road Liuyang Hi-tech Industrial Development Zone , Hunan , China	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
  - Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Airway protection face mask

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 338878
ARTG Start Date: 3/07/2020

Australian Register of Therapeutic Goods Certificate - ARTG Identifier

Medical Device Included Class 1

338713

Australian Government

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Auscanny Pty Ltd

for approval to supply

Auscanny Pty Ltd - Airway protection face mask

ARTG Identifier	338713
ARTG Start Date	1/07/2020
Product Category	Medical Device Included Class 1
GMDN	18094
GMDN Term	Airway protection face mask
Intended Purpose	Single-use, disposable device, non-sterile, intended to be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. This mask is made of blank mask, nose piece and ear loops. The blank mask is made of three layers. The inner and outer layer are non-woven fabric, the middle layer is melt-blown polypropylene.

Manufacturer Details	Address	Certificate number(s)
Hunan EEXI Technology & Service Co Ltd	No 6 North of Pingtou Road Liuyang Hi-tech Industrial Development Zone , Hunan , China	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
  - Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Airway protection face mask

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 338713
ARTG Start Date: 1/07/2020

Australian Register of Therapeutic Goods Certificate - ARTG Identifier

Medical Device Included Class 1

337857

Australian Government

Department of Health

Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Auscanny Pty Ltd

for approval to supply

Auscanny Pty Ltd - Airway protection face mask

ARTG Identifier	337857
ARTG Start Date	15/06/2020
Product Category	Medical Device Included Class 1
GMDN	18094
GMDN Term	Airway protection face mask
Intended Purpose	Single-use, disposable device, non-sterile, and intended to be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. This mask is made of blank mask, nose piece and ear loops.The blank mask is made of three layers. The inner and outer layer are non-woven fabric, the middle layer is melt-blown polypropylene.

Manufacturer Details	Address	Certificate number(s)
Hunan EEXI Technology & Service Co Ltd	No 6 North of Pingtou Road Liuyang Hi-tech Industrial Development Zone , Hunan , China	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- - The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
  - Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. Airway protection face mask

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 337857
ARTG Start Date: 15/06/2020

Brazil National Health Surveillance Agency ANVISA - Registration Number

Medical Device Class 1 – 81702110005

MINISTÉRIO DA SAÚDE

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

Este documento é para notificar que a fabricante

Hunan EEXI Technology&Service Co., Ltd.

CNPJ: 91430181MA4PHUE510

No.6, North of Pingtou road, Liuyang Hi-tech Industrial Development Zone, Hunan, China

Concluiu a notificação dos produtos a seguir perante à ANVISA – Agência Nacional de Vigilância Sanitária.

Materiais de uso médico das classes I.

NÚMERO DE REGISTRO: 81702110005

YX001 - Máscara cirúrgica descartável com elástico, tripla camada, 17,5x9,5cm

YX005 - Máscara cirúrgica descartável com elástico, tripla camada, 14,5x9cm

YX011 - Máscara cirúrgica descartável com elástico, tripla camada, 17,5x9,5cm

YX105 - Máscara cirúrgica descartável com elástico, tripla camada, 14,5x9cm

YX119 - Máscara cirúrgica descartável com tiras, tripla camada, 17,5x9,5cm

YX121 - Máscara cirúrgica descartável com tiras, tripla camada, 17,5x9,5cm

A autenticidade do registro pode ser conferida pelo seguinte procedimento:

1. Acesse http://consultas.anvisa.gov.br/
2. Clique em "Produtos para Saude"
3. Em "Número do Registro", digite 81702110005
4. Clique em "consultar"
5. Clique no produto
6. Verifique os documentos notificados e a validade do registro (VIGENTE)

Canada Medical Device Establishment Licence - Licence Number

Class 1 Manufacturer – 14507

Licence Number **14507** Numéro de la licence

Medical Device Establishment Licence

Licence d'établissement pour les instruments médicaux

HUNAN EEXI TECHNOLOGY & SERVICE CO., LTD

#6 NORTH OF PINGTOU ROAD
LINYANG HI-TECH INDUSTRIAL DEVELOPMENT ZONE
LIUYANG, HUNAN
CHINA
410300

This licence is issued in accordance with the Medical Devices Regulations of the Food and Drugs Act for the following activities:

Cette licence est délivrée conformément à la Loi sur les aliments et drogues, règlement sur les instruments médicaux pour les activités qui suivent:

	Distributor / Distributeur	Importer / Importateur	Manufacture Devices for Distribution / Fabricant d'instruments médicaux pour distribution
Class I / Classe I	No / Non	No / Non	Yes / Oui
Class II / Classe II	No / Non	No / Non	
Class III / Classe III	No / Non	No / Non	
Class IV / Classe IV	No / Non	No / Non	

Attestation made :

Attestations faites :

The establishment has documented procedures in place in respect of:		L'établissement a mis en oeuvre une procédure écrite concernant:
• distribution records	[Y]	• les registres de distribution
• complaint handling	[Y]	• les plaintes
• recalls	[Y]	• les rappels
• mandatory problem reporting	[N]	• rapports d'incident obligatoires
• handling, storage, delivery	[N]	• la manutention, le stockage, la livraison
• installation	[N]	• l'installation,
• corrective action	[N]	• les mesures correctives
• servicing	[N]	• l'entretien

Site listing begins on the back of this page

Liste des sites commence au verso de cette page

Issue Date, date de délivrance: 2020-07-17

Minister of Health Ministre de la santé	Countersigned: Director, Medical Devices Compliance Program or delegated authority Contresigné par: Directeur, Programme de la conformité des matériels médicaux ou autoritée déléguée Chad Sheehy

This licence is the property of the Medical Devices Compliance Program and must be returned upon demand.
Cette licence appartient au Programme de la conformité des matériels médicaux et doit être retournée sur demande.

Canada

Health Canada Santé Canada

Sites

HUNAN EEXI TECHNOLOGY & SERVICE CO., LTD
#6 NORTH OF PINGTOU ROAD
LINYANG HI-TECH INDUSTRIAL DEVELOPMENT ZONE
LIUYANG, HUNAN
CHINA
410300

Company ID

151728

No. d'identification de la société

Korea Textile Inspection & Testing Institute Registration Number

SUQ20-00040_M1

SUQ20-00041_M1

SUQ20-00042_M1

SUQ20-00043_M1

KOTITI 시험연구원 인류의 안전을 추구하고 미래기술을 선도하는 글로벌 비즈니스 파트너
Global Business Partner for Human Safety and Future Technology

시 험 성 적 서

KOTITI

접수번호 : 8220-1509-101001-001 발급번호 : 8135522286

접수일자 : 2020년 06월 09일 발급일자 : 2020년 06월 25일

시료명	KF94 Face Mask	검사목적	연구/참고/기타
제조번호	YX015	제조일자	-
증량/용량	-	유통(품질유지)기한	-
업체명	Hunan EEXI Technology & Service CO., Ltd	대표자	Lisa
소재지	No.6, North of Pingyou Road, Liuyang Hi-tech industrial development zone, Hunan, China	전화번호	86-15521119635

시험 항목 및 결과

시험항목	시험기준			단위	결과			비고
성상	겉면은 백색의 부직포이며, 가로 방향으로 3단으로 접혀있으며, 코 부위에는 코편이 있고, 양 측면에 탄력성이 있는 나이론 끈이 부착되어 있다.			-	겉면은 백색의 부직포이며, 가로 방향으로 3단으로 접혀있으며, 코 부위에는 코편이 있고, 양 측면에 탄력성이 있는 나이론 끈이 부착되어 있다.			자사기준 및 시험방법
형상	본체	가로	200 ± 10	mm	본체	가로	197	자사기준 및 시험방법
		세로	70 ± 10			세로	74	
	머리끈길이	좌	155 ± 15		머리끈길이	좌	141	
		우	155 ± 15			우	149	
순도시험 (색소)	위에서 관찰할 때 색을 나타내지 않는다.			-	위에서 관찰할 때 색을 나타내지 않는다.			의약외품에 관한 기준 및 시험방법
순도시험 (산 또는 알칼리)	홍색을 나타내지 않는다./ 적색을 나타내지 않는다.			-	홍색을 나타내지 않는다./ 적색을 나타내지 않는다.			의약외품에 관한 기준 및 시험방법
순도시험 (형광증백제)	형광을 나타내지 않아야 한다.			-	형광을 나타내지 않는다.			의약외품에 관한 기준 및 시험방법

시험검사자 : 조윤섭, 권수지, 권아영 기술책임자 : 왕만식

※ 위 결과는 의뢰된 시험·검사 항목만을 대상으로 한 것입니다.
※ 지면이 부족한 경우 시험·검사 항목 및 결과란은 별지로 작성 가능합니다.
※ 검사결과를 광고하거나 용기·포장 등에 표시할 때에는 시험·검사성적서 전체 내용을 모두 표시하여야 합니다.

본 시험성적서는 「식품·의약품분야 시험·검사 등에 관한 법률」에 따른 업무와 관련이 없으며, 이로 인한 법적 분쟁시 식품의약품안전처와 관련이 없음을 밝힙니다.

(사)KOTITI시험연구원

Global Business Partner

시 험 성 적 서

접수번호 : 8219-1509-100779-001 발급번호 : 8680586806

접수일자 : 2020년 05월 15일 발급일자 : 2020년 06월 19일

시험 항목 및 결과

시험항목	시험기준	단위	결과		비고
순도시험 (포름알데히드)	검액이 나타내는 색은 비교액이 나타내는 색보다 진하지 않다.	-	검액이 나타내는 색은 비교액이 나타내는 색보다 진하지 않다.		의약외품에 관한 기준 및 시험방법
분진포집효율 (염화나트륨)	개개의 측정치는 94 %이상	%	본품 : 100/100/100 전처리 : 100/100/100		보건용마스크 기준 규격에 대한 가이드라인
분진포집효율 (파라핀오일)	개개의 측정치는 94 %이상	%	본품 : 99/99/99 전처리 : 99/99/99		보건용마스크 기준 규격에 대한 가이드라인
안면부 흡기저항	개개의 측정치는 70 Pa이하	Pa	본품 : 41/33/45 전처리 : 41/43/42		보건용마스크 기준 규격에 대한 가이드라인
누설률	시험대상자 10명의 5가지 운동결과인 총 50번 누설률 시험값 중 46번의 이상이 기준값(11.0 %) 이하이어야 한다.	%	본품	1.4/0.1/0.2/0.2/1.6 6.8/7.4/5.5/5.2/6.3 0.3/1.0/0.9/1.3/0.9 3.7/1.9/8.5/8.3/1.1 1.7/10.0/5.8/2.7/2.6	보건용마스크 기준 규격에 대한 가이드라인
			전처리	2.1/3.6/4.1/6.1/4.9 0.0/0.0/0.0/0.1/0.0 4.3/4.5/6.2/9.6/3.1 2.6/2.8/3.6/7.1/5.0 1.0/3.5/0.8/10.0/2.5	
머리끈 접합부의 인장강도	검체 3개의 평균치는 10 N이상	N	50		보건용마스크 기준 규격에 대한 가이드라인

시험검사자 : 조윤섭, 권수지, 권아영 기술책임자 : 왕만식

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※ 지면이 부족한 경우 시험·검사 항목 및 결과란은 별지로 작성 가능합니다.
※ 검사결과를 광고하거나 용기·포장 등에 표시할 때에는 시험·검사성적서 전체 내용을 모두 표시하여야 합니다.

본 시험성적서는 「식품·의약품분야 시험·검사 등에 관한 법률」에 따른 업무와 관련이 없으며, 이로 인한 법적 분쟁시 식품의약품안전처와 관련이 없음을 밝힙니다.

(사)KOTITI시험연구원

시험성적서

성적서번호 : SUQ20-00040_M1

의뢰자	
업체명	Hunan EEXI Technology&Service Co.,Ltd.
이메일	overseas04@idore.com.cn
주 소	No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan,
전화번호	15521119635
팩스번호	

시료정보	
시료명	WK일회용 마스크
제품 번호	YX011
시험성적서 용도	안전기준준수확인용
제조자명	Hunan EEXI Technology&Service Co.,Ltd.
제조국	중국
비 고	

연령정보	
신청인 제시 사용 연령	14세 이상

시험방법
안전기준 부속서 1-가정용 섬유제품[국가기술표준원고시 제2018-0195호(2018.06.29)]

작성자 [signature] 확인자 Alex Hou 기술책임자 [signature] Liu Mingling

KCL (QINGDAO) TESTING SERVICE CO.,LTD. 青岛凯希尔测试技术服务有限公司 检测专用章

일 자 2020.05.26 일 자 2020.05.26 일 자 2020.05.26

비 고 : 1. 이 성적서는 의뢰자가 제시한 시료 및 시료명에 한정된 결과로서 전체제품에 대한 품질을 보증하지는 않습니다.
2. 이 성적서는 홍보, 선전, 광고 및 소송용으로 사용될 수 없으며, 용도 이외의 사용을 금합니다.

KCL (QINGDAO) TESTING SERVICE CO., LTD.
5TH FL, 2ND BD, NO.57, SHUYUNEAST ROAD, CHENGYANG DISTRICT, QINGDAO, SHANDONG, CHINA 266107
Tel: (+86)532-6696-0030 Fax: (+86)532-6895-7772
E-mail: kclqd@kcl.re.kr Website: www.kcl.re.kr

시험성적서

성적서번호 : SUQ20-00041_M1

의뢰자	
업체명	Hunan EEXI Technology&Service Co.,Ltd.
이메일	overseas04@idore.com.cn
주 소	No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan,
전화번호	15521119635
팩스번호	

시료정보	
시료명	간편FH 일회용마스크
제품 번호	YX002
시험성적서 용도	안전기준준수확인용
제조자명	Hunan EEXI Technology&Service Co.,Ltd.
제조국	중국
비 고	

연령정보	
신청인 제시 사용 연령	14세 이상

시험방법
안전기준 부속서 1-가정용 섬유제품[국가기술표준원고시 제2018-0195호(2018.06.29)]

작성자 [signature] 확인자 Alex Hou 기술책임자 [signature] Liu Mingling

KCL (QINGDAO) TESTING SERVICE CO., LTD. 检测专用章

일 자 2020.05.26 일 자 2020.05.26 일 자 2020.05.26

비 고 : 1. 이 성적서는 의뢰자가 제시한 시료 및 시료명에 한정된 결과로서 전체제품에 대한 품질을 보증하지는 않습니다.
2. 이 성적서는 홍보, 선전, 광고 및 소송용으로 사용될 수 없으며, 용도 이외의 사용을 금합니다.

KCL (QINGDAO) TESTING SERVICE CO., LTD.
5TH FL, 2ND BD, NO.57, SHUYUNEAST ROAD, CHENGYANG DISTRICT, QINGDAO, SHANDONG, CHINA 266107
Tel: (+86)532-6696-0030 Fax: (+86)532-6895-7772
E-mail: kclqd@kcl.re.kr Website: www.kcl.re.kr

시험성적서

성적서번호 : SUQ20-00042_M1

의뢰자	
업체명	Hunan EEXI Technology&Service Co.,Ltd.
이메일	overseas04@idore.com.cn
주 소	No.6, North of Pingtou road, Liuyang Hi-tech industrial development zone, Hunan,
전화번호	15521119635
팩스번호	

시료정보	
시료명	일회용YY마스크
제품 번호	YX001
시험성적서 용도	안전기준준수확인용
제조자명	Hunan EEXI Technology&Service Co.,Ltd.
제조국	중국
비 고	

연령정보	
신청인 제시 사용 연령	14세 이상

시험방법
안전기준 부속서 1-가정용 섬유제품[국가기술표준원고시 제2018-0195호(2018.06.29)]

작성자 [signature] 확인자 Alex Hou 기술책임자 [signature]

일 자 2020.05.26 일 자 2020.05.26 일 자 2020.05.26

비 고 : 1. 이 성적서는 의뢰자가 제시한 시료 및 시료명에 한정된 결과로서 전체제품에 대한 품질을 보증하지는 않습니다.
2. 이 성적서는 홍보, 선전, 광고 및 소송용으로 사용될 수 없으며, 용도 이외의 사용을 금합니다.

KCL (QINGDAO) TESTING SERVICE CO., LTD.
5TH FL., 2ND BD, NO.57, SHUYUNEAST ROAD, CHENGYANG DISTRICT, QINGDAO, SHANDONG, CHINA 266107
Tel: (+86)532-6696-0030 Fax: (+86)532-6895-7772
E-mail: kclqd@kcl.re.kr Website: www.kcl.re.kr

시험성적서

성적서번호 : SUQ20-00043_M1

의뢰자	
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팩스번호	

시료정보	
시료명	아동용마스크
제품 법흐	YX005
시험성적서 용도	공급자적합성확인용
제조자명	Hunan EEXI Technology&Service Co.,Ltd.
제조국	중국
비 고	

연령정보	
신청인 제시 사용 연령	6세-12세

시험방법
공급자적합성 안전기준 부속서 15-아동용 섬유제품[산업통상자원부고시 제2018-0031호(2018.03.05)] 어린이제품 공통안전기준[산업통상자원부고시 제2017-18호(2017.01.31)]

작성자 [signature] 확인자 Alex Hou 기술책임자 青岛 Liu Mingling

KCL (QINGDAO) TESTING SERVICE CO., LTD. 检测专用章

일 자 2020.05.26 일 자 2020.05.26 일 자 2020.05.26

비 고 : 1. 이 성적서는 의뢰자가 제시한 시료 및 시료명에 한정된 결과로서 전체제품에 대한 품질을 보증하지는 않습니다.
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3. • 외주시험

KCL (QINGDAO) TESTING SERVICE CO., LTD.
5TH FL, 2ND BD, NO.57, SHUYUNEAST ROAD, CHENGYANG DISTRICT, QINGDAO, SHANDONG, CHINA 266107
Tel: (+86)532-6696-0030 Fax: (+86)532-6895-7772
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Taiwan Ministry of Health and Welfare Medical Device Manufacturing No.

008382

衛生福利部食品藥物管理署
Food and Drug Administration,Ministry of Health and Welfare

西藥、醫療器材、化粧品許可證查詢

詳細處方成分 | 藥物外觀 | 仿單/外盒資料 | 授權使用 | 健保藥價查詢 | 離 開

許可證詳細內容

＊＊＊ 衛部醫器製壹字第008382號 ＊＊＊

註銷狀態		註銷日期	
註銷理由		製造許可登錄編號	
有效日期	114/06/09	發證日期	109/06/09
許可證種類	醫　器		
舊證字號		醫療器材級數	第一等級
通關簽審文件編號			
中文品名	"上好"醫療防護口罩(未滅菌)		
英文品名	"S. H." Medical Face Mask(Non-sterile)		
效能	限醫療器材管理辦法「醫療用衣物(I.4040)」第一等級鑑別範圍。		
醫器規格	空白		
劑型		包裝	
標籤、仿單及包裝加註			
醫器主類別一	I一般及整型外科手術裝置	醫器次類別一	I4040醫療用衣物
醫器主類別二		醫器次類別二	
醫器主類別三		醫器次類別三	
藥品分類		監視期限	
主成分略述			

https://info.fda.gov.tw/MLMS/H0001D.aspx?Type=Lic&LicId=93008382

ISO9001:2015

Certificate No: USA20Q40924R0M

Certificate

Certificate No.: USA20Q40924R0M

This is to certify that the Quality Management System of

HUNAN EEXI TECHNOLOGY & SERVICE CO., LTD.

Unified Social Credit Code: 91430181MA4PHUE510

Registered/Office Address: No.6 North of Pingtou Road, Liuyang Hi-Tech Industrial Development Zone, Hunan, China

Production Address: Floor 1 and 2, Building 3, No.6 North of Pingtou Road, Liuyang Hi-Tech Industrial Development Zone, Hunan, China

Has been audited to conform to the following Quality Management System standard

ISO 9001:2015

This Quality Management System is valid for the

The production of disposable medical masks (non-sterile), disposable medical masks (sterile), medical surgical masks (non-sterile) and medical surgical masks (sterile) (within the company's license scope)

Date of initial issuance: Apr. 20, 2020

Date of issuance: Apr. 20, 2020

Date of renewal: May. 12, 2020

Date of expiry: Apr. 19, 2023

Issued by: Wu Fengru

Beijing East Allreach Certification Center Co., Ltd.

The certificate will remain valid only if the certified organization accepts surveillance audit at regular intervals and is audited to be qualified. The information of this certificate is available at EACC website (www.eacc.com.cn) and CNCA' s official website (www.cnca.gov.cn), and it' s also available by scanning the QR Code in the lower right corner.

EACC address:1st Floor, No. 121 building, No. 17, Jingshengnansi Street, Jinqiao Science & Technology Industrial Base,Tongzhou Park of Zhongguancun Science & Technology Zone, Tongzhou District, Beijing 101102

ISO 14001:2015

Certificate No: USA20E40925R0M

Certificate

Certificate No.: USA20E40925R0M

This is to certify that the Environmental Management System of

HUNAN EEXI TECHNOLOGY & SERVICE CO., LTD.

Unified Social Credit Code: 91430181MA4PHUE510

Registered/Office Address: No.6 North of Pingtou Road, Liuyang Hi-Tech Industrial Development Zone, Hunan, China

Production Address: Floor 1 and 2, Building 3, No.6 North of Pingtou Road, Liuyang Hi-Tech Industrial Development Zone, Hunan, China

Has been audited to conform to the following Environmental Management System standard

ISO 14001:2015

This Environmental Management System is valid for the

The production of disposable medical masks (non-sterile), disposable medical masks (sterile), medical surgical masks (non-sterile) and medical surgical masks (sterile) (within the company's license scope) and related environmental management activities of involved sites

Date of initial issuance: Apr. 20, 2020

Date of issuance: Apr. 20, 2020

Date of renewal: May. 12, 2020

Date of expiry: Apr. 19, 2023

Issued by: Wu Fengru

Beijing East Allreach Certification Center Co., Ltd.

The certificate will remain valid only if the certified organization accepts surveillance audit at regular intervals and is audited to be qualified. The information of this certificate is available at EACC website (www.eacc.com.cn) and CNCA' s official website (www.cnca.gov.cn), and it' s also available by scanning the QR Code in the lower right corner.

EACC address:1st Floor, No. 121 building, No. 17, Jingshengnansi Street, Jinqiao Science & Technology Industrial Base,Tongzhou Park of Zhongguancun Science & Technology Zone, Tongzhou District, Beijing 101102

EN ISO 13485:2016

Certificate No: CN20/42091

Certificate CN20/42091

The management system of

Hunan EEXI Technology & Service Co., Ltd.

No. 6, North of Pingtou Road, Liuyang Hi-tech Industrial Development Zone,
Hunan Province, 410300, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design and manufacture of non-sterile surgical face mask, non-sterile single use medical face mask and non-sterile medical protective face mask

This certificate is valid from 16 June 2020 until 15 June 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 5 June 2023
Issue 1. Certified since 16 June 2020

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

Viral Filtration Efficiency (VFE) in ASTM F2101

Proven that Curie technology can effectively **filter virus (>99.9a%)**

Nelson Labs.
A Sotera Health company

Sponsor:
Eddie Yam
Intertek Testing Services Hong Kong Ltd.
1/F, Garment Centre, 576 Castle Peak Road
Kowloon,
HONG KONG

Viral Filtration Efficiency (VFE) Final Report

Test Article:	modified non-woven colour: White Style #1001
Study Number:	1280865-S01
Study Received Date:	25 Mar 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0007 Rev 16
Deviation(s):	None

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.1 - 3.3 x 10^3 plaque forming units (PFU) with a mean particle size (MPS) of 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure was adapted from ASTM F2101.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Either
Test Area:	~40 cm^2
VFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	1.6 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	2.9 µm

Study Director — James W. Luskin — Study Completion Date: 09 Apr 2020

1280865-S01

Results:

Test Article Number	Percent VFE (%)
1	>99.9[a]
2	>99.9[a]
3	>99.9[a]
4	>99.9[a]
5	>99.9[a]

[a] There were no detected plaques on any of the Andersen sampler plates for this test article.

The filtration efficiency percentages were calculated using the following equation:

$$\%\,VFE = \frac{C - T}{C}\ x\ 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Bacterial Filtration Efficiency with Increased Delivery Challenge (BFE) in ASTM F2101 and EN14683

Proven that Curie technology can effectively filter increased challenge of bacteria (99.8%)

Nelson Labs.
A Sotera Health company

Sponsor:
Wong Chak Ming
Hong Kong Medical Supply Limited
Unit A3, 2F Mai Wah Industrial Bldg.
1-7 Wah Sing Street
Hong Kong,
CHINA

Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	HKMSLMASK000
Purchase Order:	HKMSLPO20200326
Study Number:	1282265-S01
Study Received Date:	28 Mar 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 3.5×10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B; with the exception of the higher challenge level, which may represent a more severe test.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~176 mm x ~160 mm
Positive Control Average:	3.5×10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.0 µm

The positive control average was out of specification per STP0004 Rev 18 section 6.1 which states, "The BFE positive control average shall be maintained at $1.7\text{-}3.0 \times 10^3$ CFU." Testing with a more severe challenge to the test articles represents a worse case. The sponsor accepted the use of the higher challenge; therefore, the results are considered valid at the testing conditions that occurred.

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Study Director — for James W. Luskin — 20 Apr 2020 Study Completion Date

1282265-S01

Results:

Test Article Number	Percent BFE (%)
1	99.8
2	99.8
3	99.8
4	99.8
5	99.8

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Viral Filtration Efficiency (VFE) in ASTM F2101

Proven that Curie technology can effectively filter virus (>99.9a%)

intertek
Total Quality. Assured.

Number: HKGT05112613-S1

TEST REPORT

Applicant: CURIE LIMITED
B3-1 G/F
SUPERLUCK INDL CTR PHASE 2
57 SHA TSUI RD
TSUEN WAN NT HK

Attn: ALDRIN OR

Date: Apr 22, 2020
This is to supersede report no. HKGT05112613 dated Apr 21, 2020

Sample Description As Declared :

No. Of Sample	:	Several
Buyer's Name	:	-
Agent's Name	:	-
Manufacturer's Name	:	Curie Limited
Sample Description	:	Curie Ultrahigh-Efficiency Viral Filter超高效病毒濾材
Colour	:	White
Style No.	:	1001
Order No. / PO No.	:	-
Product End Uses	:	-
Fibre Content	:	Nonwoven
Fabric/GMT Weight	:	20g
Ref.	:	-

Date Received/Date Test Started : Apr 15, 2020

Applicant's Provided Care Instruction/Label :

-

intertek
Total Quality. Assured.

Number: HKGT05112613-S1

TEST REPORT

Original Sample Photo:

For any queries on this report, you are welcome to contact our customer service representatives:

US3
Angie Yu (852) 98639123 or email to angie.yu@intertek.com

intertek
Total Quality. Assured.

Number: HKGT05112613-S1

TEST REPORT

Tests Conducted (As Requested By The Applicant)

1 Evaluation of Viral Filtration Efficiency (VFE):

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage ΦX174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at $1.1 - 3.3 \times 10^3$ plaque forming units (PFU) with a mean particle size (MPS) of 3.0 ± 0.3 μm. The aerosols droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure was adapted from ASTM F2101.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test side: Either

Test Area: ~40 cm²

VFE Flow Rate: 28.3 Liters per minute (L/min)

Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5 °C for a minimum of 4 hours

Positive Control Average: 1.6×10^3 PFU

Negative Monitor Count: <1 PFU

MPS: 2.9 μm

intertek
Total Quality. Assured.

Number: HKGT05112613-S1

TEST REPORT

Tests Conducted (As Requested By The Applicant)

Evaluation of Viral Filtration Efficiency (Cont'd)

Result:

Test Article Number	Percent VFE (%)
1	>99.9[a]
2	>99.9[a]
3	>99.9[a]
4	>99.9[a]
5	>99.9[a]

[a] There were no detected plaques on any of the Andersen sampler plates for this test article.

The filtration efficiency percentages were calculated using the following equation:

$$\%VFE = \frac{C - T}{C} x100$$

C= Positive control average
T= Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Remark: The test was conducted by competent subcontractor lab.

End of Report

Bacterial Filtration Efficiency (BFE) in ASTM F2101 and EN14683

Proven that Curie technology can effectively filter bacteria (99.9%), complying ASTM F2101 Level 3 and EN14683 Type IIR

Air Exchange Pressure in ASTM F2101 / EN14683

Proven that air exchange pressure of KV99 masks can comply with standards of ASTM F2101 Level 3 and EN14683 Type IIR

Nelson Labs.
A Sotera Health company

Sponsor:
Wing Wah Medicine Group Holdings Limited
1/F Ching Cheong Industrial Building
1-7 Kwai Chong Rd
Kwai Chung, NT

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	4 Ply Disposable Medical Mask Colour: White Fiber Content: Curie Biohazard Filter + SS Non-Woven
Purchase Order:	R904838210
Study Number:	1334934-S01
Study Received Date:	25 Aug 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~175 mm x ~165 mm
Positive Control Average:	2.0 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.0 µm

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Leah Tiberius electronically approved for — 18 Sep 2020 16:53 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	>99.9
2	99.9
3	>99.9[a]
4	>99.9
5	99.8

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	5.2	50.6
2	5.2	50.5
3	5.4	52.6
4	5.3	51.5
5	4.8	47.5

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Microbial Cleanliness (Bioburden) of Medical Masks in EN14683

Proven that total bioburden of KV99 can comply with standard of EN14683 Type IIR (<6 cfu)

Nelson Labs
A Sotera Health company

Sponsor:
Wing Wah Medicine Group Holdings Limited
1/F Ching Cheong Industrial Building
1-7 Kwai Chong Rd
Kwai Chung, NT
HONG KONG

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	4 Ply Disposable Medical Mask Colour: White Fiber Content: Curie Biohazard Filter + SS Non-Woven
Purchase Order:	R904838210
Study Number:	1334930-S01
Study Received Date:	25 Aug 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0036 Rev 15 Customer Specification Sheet (CSS) Number: 202002096 Rev 01
Deviation(s):	None

Summary: The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Robert Putnam electronically approved
Study Director Robert Putnam

24 Sep 2020 02:10 (+00:00)
Study Completion Date and Time

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	4.3	<3	<3	<5.7	<1.3
2	4.3	6	<3	<8.9	<2.1
3	4.2	<3	<3	<5.8	<1.4
4	4.2	3	<3	<6.0	<1.4
5	4.2	<3	<3	<6.0	<1.4
Recovery Efficiency	UTD[a]				

< = No Organisms Detected
UTD = Unable to Determine
Note: The results are reported as colony forming units per test article.
[a] UTD due to zero count on the first rinse. An alternative method or inoculated product recovery efficiency is recommended.

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	0%

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results. The number of masks to be tested shall be a minimum of 5 or more to meet an acceptable quality level of 4%. The bioburden of the medical mask shall be < 30 CFU/g tested.

Procedure:

Positive Controls/Monitors:	*Bacillus atrophaeus*
Extract Fluid:	Peptone Tween®
Extract Fluid Volume:	~300 mL
Extract Method:	Orbital Shaking for 15 minutes at 250 rpm
Plating Method:	Membrane Filtration
Agar Medium:	Tryptic Soy Agar Potato Dextrose Agar
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3-7 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 5-7 days at 20-25°C, then enumerated.

Synthetic Blood Penetration Pressure in ASTM F2101 / ASTM F1862 / EN14683

Proven that KV99 mask can effectively intercept fluid (160mmHg) from penetration, complying ASTM F2101 Level 3 and EN14683 Type IIR

Nelson Labs.
A Sotera Health company

Sponsor:
Wing Wah Medicine Group Holdings Limited
1/F Ching Cheong Industrial Building
1-7 Kwai Cheong Road
Kwai Chung, NT

Synthetic Blood Penetration Resistance Final Report

Test Article:	4 Ply Disposable Medical Mask Colour: White Fiber Content: Curie Biohazard Filter + SS Non-Woven
Purchase Order:	R904838210
Study Number:	1334931-S01
Study Received Date:	25 Aug 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	32
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	23.2°C and 22% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 160 mmHg (21.3 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Study Director FOR James W. Luskin

17 SEP 2020
Study Completion Date

1334931-S01

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com

Sub-Micron Particulate Filtration Efficiency (0.1μm PSL) in ASTM F2101 / ASTM F2299 / EN14683

Proven that KV99 masks can effectively filter 0.1μm sub-micron particulate (>99.8%), complying ASTM F2101 Level 3 and EN14683 Type IIR

Nelson Labs
A Sotera Health company

Sponsor:
Wing Wah Medicine Group Holdings Limited
1/F Ching Cheong Industrial Building,
1-7 Kwai Chong Rd,
Kwai Chung, NT

Latex Particle Challenge Final Report

Test Article:	4 Ply Disposable Medical Mask Colour: White Fiber Content: Curie Biohazard Filter + SS Non-Woven
Purchase Order:	R904838210
Study Number:	1334932-S01
Study Received Date:	25 Aug 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0005 Rev 08
Deviation(s):	None

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values. During testing and controls, the air flow rate is maintained at 1 cubic foot per minute (CFM) ± 5%.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
Area Tested:	91.5 cm^2
Particle Size:	0.1 μm
Laboratory Conditions:	21°C, 28% relative humidity (RH) at 1813; 21°C, 28% RH at 1911
Average Filtration Efficiency:	99.86%
Standard Deviation:	0.038

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Trang Truong electronically approved for Curtis Gerow
Study Director

16 Sep 2020 22:26 (+00:00)
Study Completion Date and Time

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	9	10,448	99.914
2	17	11,356	99.85
3	22	12,202	99.82
4	19	12,264	99.85
5	13	12,067	99.89

Standard for the Flammability of Clothing Textiles - US 16 CFR Part 1610

Proven that KV99 masks can comply with Class 1 - Normal Flammability

intertek
Total Quality. Assured.

Issuing Laboratory:
Intertek Testing Services Hong Kong Ltd.
Hong Kong Accreditation Service (HKAS) has accredited this laboratory (Reg. No. HOKLAS 005) under Hong Kong Laboratory Accreditation Scheme (HOKLAS) for specific laboratory activities as listed in the HOKLAS Directory of Accredited Laboratories.

Number: HKGT05148314

TEST REPORT

Applicant: WING WAH MEDICINE GROUP HOLDINGS LIMITED
1/F CHING CHEONG IND BLDG
1-7 KWAI CHEONG RD
KWAI CHUNG NT
HK

Attn: ANNIE AU

Date: Sep 28, 2020

Sample Description As Declared :

No. Of Sample	: Several
Buyer's Name	: -
Agent's Name	: -
Manufacturer's Name	: -
Sample Description	: 4 Ply Disposable Medical Mask
Colour	: White
Style No.	: -
Order No. / PO No.	: -
Product End Uses	: -
Fibre Content	: Curie Biohazard Filter + SS Non-Woven
Fabric/GMT Weight	: -
Ref.	: -

Date Received/Date Test Started : Aug 18, 2020

Applicant's Provided Care Instruction/Label :
-

For and on behalf of
Intertek Testing Services HK Ltd

WONG Sai Ming
Technical Supervisor II

Intertek Testing Services Hong Kong Limited
2/F, Garment Centre,
576 Castle Peak Road,
Kowloon, Hong Kong SAR, China
Tel +852 2173 8888
Fax +852 2786 1903
intertek.com.hk

Issuing Laboratory:
Intertek Testing Services Hong Kong Ltd.
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Number: HKGT05148314

TEST REPORT

Tests Conducted (As Requested By The Applicant)

1 Flammability of 45 degree angle test (US 16 CFR Part 1610 - Standard for the Flammability of Clothing Textiles):

[X] Plain Surface [ ] Raised Surface

Prelim Plain Surface:
Length : IBE
Width : IBE

Burn Direction:	☒ Length ☐ Width
	Original (seconds)
1.	IBE
2.	IBE
3.	DNI
4.	IBE
5.	DNI
6.	-
7.	-
8.	-
9.	-
10.	-

Intertek Testing Services Hong Kong Limited
2/F, Garment Centre,
576 Castle Peak Road,
Kowloon, Hong Kong SAR, China
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Number: HKGT05148314

TEST REPORT

Tests Conducted (As Requested By The Applicant)

Flammability of 45 degree angle test (Cont'd)

Classification:	☒	Class 1,	Normal Flammability
	☐	Class 2,	Intermediate Flammability, Raised Surface
	☐	Class 3,	Rapid And Intense Burning,

Explanation Of Flammability Results:

DNI	Did not ignite.
IBE	Ignited but extinguished.
_.._ sec.	Actual burn time measured and recorded by the timing device.
SF uc	Surface flash, under the stop thread, but does not break the stop thread.
SF pw	Surface flash, part way. No time shown because the surface flash did not reach the stop thread.
SF poi	Surface flash, at point of impingement only(equivalent to "Did not ignite" for plain surfaces).
_.._ SF only	Time in seconds, surface flash only. No damage to the base fabric.
_.._ SFBB	Time in seconds, surface flash base burn starting at places other than the point of impingement as a result of surface flash
_.._ SFBB poi	Time in seconds, surface flash base burn starting at the point of impingement.
_.._ SFBB poi*	Time in seconds, surface flash base burn possibly starting at the point of impingement. The asterisk is accompanied by the following statement : "Unable to make absolute determination as to source of base burns." This statement is added to the result of any specimen if there is a question as to origin of the base burn.

End of Report

Intertek Testing Services Hong Kong Limited
2/F, Garment Centre,
576 Castle Peak Road,
Kowloon, Hong Kong SAR, China
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Fax +852 2786 1903
intertek.com.hk

Determination of Antiviral Activity of Textile Products BS ISO 18184

Proven that Curie technology can effectively **kill COVID-19 Coronavirus** SARS-CoV-2 (**>99.81%**)

ATCCR

Report No: ATCCR20081010F

Test Report

Sample Category	Curie Ultrahigh-Efficiency Viral Filter for KV-99
Client	Curie Limited
Test Category	Test Entrust
Date of Report	2020.08.18

北京京畿分析测试中心有限公司

Analytical and Testing Center of Capital Regions

Report No: ATCCR20081010F

Detection Information

Client	Curie Limited		Sample Source	Inspect
Client address	Room C,23/F,Tsuen Tung Factory Building,38-40 Chai Wan KOK Street, Tsuen Wan,Hong Kong		Sample State	Normal
Date of Receives samples	2020.08.10		Date(s) of tests	2020.08.10-2020.08.18
Sample No	ATCCR20081010F-0810CP01			
Category	Test Project	Test Standard and Method		Test Instruments
Curie Ultrahigh-Efficiency Viral Filter for KV-99	Antiviral Activity Value (COVID-19)	ISO 18184:2019 Textiles Determination of antiviral		Biosafety Cabinet

End

Remarks	Production units: Curie Limited Trademarks: Curie Date of production: 2020.06.09 Sample model: Curie Ultrahigh-Efficiency Viral Filter for KV-99 Sample batch: 1001

Report Preparer: 刘畅

Report Reviewer:

Authorized Signatory:

t Date of Issues Repor: 2020.08.18

(Special Chapter for Inspection and Inspection)

Test results

Virus Types	(NO)	lg(Va_{0h})（lgTCID$_{50}$/mL）	lg(Vb_{2h})（lgTCID$_{50}$/mL）	lg(Vc_{2h})（lgTCID$_{50}$/mL）
COVID-19 virus MDCK cells	1	6.73	6.68	3.7
	2	6.68	6.56	4
	3	6.7	6.57	3.9
Average Value of lgTCID$_{50}$/mL		6.70	6.61	3.88
Antiviral Activity Value		2.72		
Antiviral Activity Rate (%)		99.81		

End

Beijing Shantong Medical Testing Laboratory

Declaration of Test Results

Beijing Shantong Medical Testing Lab "BSMTL" hereby declares that the test item described below has been tested by BSMTL and complies with the requirements of

ISO 18184: 2019 Textile Determination of Antiviral

The complete detail of the tests performed and the results are recorded in
Report No: ATCCR20081010F Dated: 18.08.2020

Description of item tested: *Curie Ultrahigh-Efficiency Viral Filter for KV-99*

Virus Tested: SARS-COV-2 / COVID-19 MDCK Cells

Summary of test results -

Antiviral Activity Value: ***2.72***

Antiviral Activity Rate: ***99.81%***

Submitted by: *Curie Limited*
Room C, 23/F,Tsuen Tung Factory Building,38-40 Chai Wan Kok Street, Tsuen Wan, Hong Kong SAR

Declaration authorised by:

Name: 赵志刚

Title: 实验室负责人

Date: 02/09/2020

Attention is drawn to the conditions upon which this declaration is issued, namely:

1. *This declaration does not indicate provide or imply any measure of Approval, Certification, Supervision, Control or Surveillance by BSMTL to this or any related product.*
2. *This Declaration applied only to the particular sample tested and to the specific tests carried out as detailed in the Report referred to above.*
3. *The general and specific conditions of the BSMTL Conditions of Contract for Testing, apply in all respects.*

统一社会信用代码

91110111MA01A4KK4D

营业执照

(副 本) (1-1)

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息

名　　称　北京普通医学检验实验室有限公司

类　　型　有限责任公司(法人独资)

法定代表人　杨益

经营范围　医学检验医疗服务；技术开发、技术转让、技术咨询、技术服务。（企业依法自主选择经营项目，开展经营活动；医疗服务以及依法须经批准的项目，经相关部门批准后依批准的内容开展经营活动；不得从事本市产业政策禁止和限制类项目的经营活动。）

注册资本　600万元

成立日期　2018年01月24日

营业期限　2018年01月24日 至 2048年01月23日

住　　所　北京市房山区拱辰街道办事处学园北街11号综合服务楼一层5106

登记机关　北京市工商行政管理局房山分局

2019年 05月 28日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

中华人民共和国

医疗机构执业许可证

机构名称 北京善通医学检验实验室

法定代表人 杨益

地　　址 北京市房山区拱辰街道办事处学园北街1号综合服务楼一层

主要负责人 赵志国

诊疗科目 医学检验科；临床免疫、血清学专业；临床细胞分子遗传学专业******

登记号 007913110111417919

有效期限 自 2019年 07月 02日至 2022 年 12月 30 日

该医疗机构经核准登记，准予执业

中华人民共和国国家卫生和计划生育委员会

发证机关 北京市房山区卫生健康委员会

发证日期 2019 年 8月 14日

开户许可证

核准号：J1000210464502

编 号：1000-03577720

经审核，北京善通医学检验实验室有限公司 符合开户条件，准予开立基本存款账户。

法定代表人（单位负责人）杨益

开户银行 兴业银行股份有限公司北京房山支行

账　号 321580100100032556

发证机关（盖章）

2018年11月16日

北京市卫生健康委员会

北京市卫生健康委员会关于同意密云区医院等11家检测机构开展新型冠状病毒核酸检测的通知

西城区、朝阳区、丰台区、房山区、顺义区、大兴区、密云区卫生健康委，经济开发区，市疾控中心，市医学检验质控中心，各相关医疗机构：

根据北京市密云区医院、北京市西城区展览路医院、北京市丰台区铁营医院、北京市朝阳区三环肿瘤医院、北京朝阳急诊抢救中心、北京朝阳中西医结合急诊抢救中心、北京市大兴区中西医结合医院、北京北亚骨科医院、北京德威铭达医学检验所、北京善通医学检验实验室和北京索真医学检验实验室等11家检测机构（以下简称11家检测机构）提交的开展新冠病毒核酸检测的申请，结合专家评估意见，经研究，现就有关事项通知如下：

一、同意11家检测机构开展新型冠状病毒核酸检测工作。

二、11家检测机构要严格按照国家和本市关于开展新型冠状病毒核酸检测、生物安全防护、生物样本资源管理的有

北京市病原微生物实验室及实验室活动备案通知书

京房山卫实验室备字[2020]第043号

北京善通医学检验实验室有限公司 ：

你单位于2020年06月27日提交的北京市病原微生物实验室及实验活动备案材料如下：

1. ☑《北京市病原微生物实验室及实验室活动备案表》；

2. ☑ 实验室或实验室设立单位的法人资格证明；

3. ☑ 实验室设立单位生物安全组织管理框架图；

4. ☑ 实验室布局平面图；

经本机关审查，认为申请材料齐全、符合《北京市病原微生物实验室及实验活动备案管理办法》的要求，决定予以备案。

卫生健康行政部门（印章）

2020年06月27日

备注：此备案旨在了解你单位实验室及其实验活动基本状况，不作为审批依据。请你单位备案后，严格按照《中华人民共和国传染病法》、《病原微生物实验室生物安全管理条例》和《人间传染的高致病性病原微生物实验室和实验活动生物安全审批管理办法》等相关法律法规规定，从事相关实验活动，规范实验室管理。

北京市卫生健康委员会制定

Sub-Micron Particulate Filtration Efficiency (0.1μm PSL) in ASTM F2101 / ASTM F2299 / EN14683

Proven that KV99 masks can effectively filter 0.1μm sub-micron particulate (>99%), complying ASTM F2101 Level 3 and EN14683 Type IIR

Air Exchange Pressure in ASTM F2101 / EN14683

Proven that air exchange pressure of KV99 masks can comply with standards of ASTM F2101 Level 3 and EN14683 Type IIR

TTRI 財團法人紡織產業綜合研究所 Taiwan Textile Research Institute

TEST REPORT TUCHENG

Date: Aug.31,2020 Date of Receipt: Aug.24,2020

Report No.: TFF9H598 Quantity: 1PC Page Order/Pages: (P1/5) Ref. No.: NIL

Report Title: Curie Limited(U3104) Item: Mask

Address: No. 108, Ganhe Rd., Xitun Dist., Taichung City 407, Taiwan

Test Items		Test Results	Test Methods
Sub-Micron Particulate Filtration Efficiency(%) (0.1μm PSL)	1	99.49	ASTM F2100-2019 9.3 ASTM F2299-2017 Flow rate:28.1 (Liter/min)
	2	99.45	
	3	99.46	
	4	99.48	
	5	99.48	
	Ave.	99.47	
Air Exchange Pressure (mmH2O/cm²)	1	5.3	ASTM F2100-2019 9.2 EN 14683:2019 Annex C
	2	5.3	
	3	4.9	
	4	5.1	
	5	5.3	
Flammability (as Received)		DNI	ASTM F2100-2019 9.5 CPSC 16 CFR 1610-2008

Note: 1mmH2O=9.8Pa.

Note: Air Exchange Pressure takes 5 pieces for testing.

Note: Flammability takes 20 samples for testing.

Note: "DNI":Did Not Ignite.

Note: Sample description is given by the client: Brandname: Curie
Model: Curie KV99 Face Mask
Hong Kong address: Unit C, 23F, Tsun Tung Factory Bldg 38-40
Chai Wan Kok St, Tsuen Wan. NT Hong Kong

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

Authorized by president of Taiwan Textile Research Institute

Jui-hung Kao
Director, Department of Testing and Certification

Department of Testing and Certification, Taiwan Textile Research Institute
No.6, Chengtian Rd., Tucheng Dist., New Taipei City 23674, Taiwan (R.O.C.)
Tel : +886-2-22670321 ext. 7107, 7110
Fax : +886-2-22675108 , +886-2-22689839

TTRI 財團法人紡織產業綜合研究所 Taiwan Textile Research Institute

TEST REPORT TUCHENG

Date: Aug.31,2020 Date of Receipt: Aug.24,2020

Report No.: TFF9H599 Quantity: 1PC Page Order/Pages: (P1/5) Ref. No.: NIL

Report Title: Curie Limited(U3104) Item: Mask

Address: No. 108, Ganhe Rd., Xitun Dist., Taichung City 407, Taiwan

Test Items		Test Results	Test Methods
Air Exchange Pressure (Pa/cm²)	1	50.7	EN 14683:2019 Annex C
	2	49.1	
	3	49.7	
	4	51.3	
	5	48.8	

Note: Sample description is given by the client: Brandname: Curie
Model: Curie KV99 Face Mask
Hong Kong address: Unit C, 23F, Tsun Tung Factory Bldg 38-40
Chai Wan Kok St, Tsuen Wan. NT Hong Kong

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

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3.The test report should not be used for public advertisement and commercial promotion.

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Director, Department of Testing and Certification

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Tel : +886-2-22670321 ext. 7107, 7110
Fax : +886-2-22675108 , +886-2-22689839

Synthetic Blood Penetration Pressure in ASTM F2101 / ASTM F1862 / EN14683

Proven that KV99 mask can effectively intercept fluid (160mmHg) from penetration, complying ASTM F2101 Level 3 and EN14683 Type IIR

TTRI 財團法人紡織產業綜合研究所 Taiwan Textile Research Institute

TEST REPORT TUCHENG

Date: Aug.07,2020 Date of Receipt: Jul.27,2020

Report No.: TAG9G706 Quantity: 1PC Page Order/Pages: (P2/5) Ref. No.: NIL

Report Title: Curie Limited(U3104) Item: Mask

Address: No. 108, Ganhe Rd., Xitun Dist., Taichung City 407, Taiwan

Test Items		Test Results	Test Methods
Synthetic Blood Penetration Pressure:160 mmHg	1	None Seen	ASTM F2100-2019 9.4
	2	None Seen	ASTM F1862-2017
	3	None Seen	
	4	None Seen	
	5	None Seen	
	6	None Seen	
	7	None Seen	
	8	None Seen	
	9	None Seen	
	10	None Seen	
	11	None Seen	
	12	None Seen	
	13	None Seen	
	14	None Seen	
	15	None Seen	
	16	None Seen	

Note: Sample description is given by the client: Brandname: Curie
Model: Curie KV99 Face Mask
Hong Kong address: Unit C, 23F, Tsun Tung Factory Bldg 38-40
Chai Wan Kok St, Tsuen Wan. NT Hong Kong

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

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TTRI 財團法人紡織產業綜合研究所
Taiwan Textile Research Institute

TEST REPORT TUCHENG

Date: Aug.31,2020 Date of Receipt: Aug.24,2020

Report No.: TFF9H599 Quantity: 1PC Page Order/Pages: (P2/5) Ref. No.: NIL

Report Title: Curie Limited(U3104) Item: Mask

Address: No. 108, Ganhe Rd., Xitun Dist., Taichung City 407, Taiwan

Test Items		Test Results	Test Methods
Synthetic Blood Penetration	1	None Seen	EN 14683:2019
Pressure:120 mmHg (16.0 kPa)	2	None Seen	ISO 22609:2004
	3	None Seen	
	4	None Seen	
	5	None Seen	
	6	None Seen	
	7	penetration	
	8	None Seen	
	9	None Seen	
	10	None Seen	
	11	None Seen	
	12	None Seen	
	13	None Seen	
	14	None Seen	
	15	None Seen	
	16	None Seen	

Note: Sample description is given by the client: Brandname: Curie
Model: Curie KV99 Face Mask
Hong Kong address: Unit C, 23F, Tsun Tung Factory Bldg 38-40
Chai Wan Kok St, Tsuen Wan. NT Hong Kong

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

Authorized by president of
Taiwan Textile Research Institute

Jui-hung Kao
Director,
Department of Testing and Certification

Department of Testing and Certification, Taiwan Textile Research Institute
No.6, Chengtian Rd., Tucheng Dist., New Taipei City 23674, Taiwan (R.O.C.)
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TTRI 財團法人紡織產業綜合研究所 Taiwan Textile Research Institute

TEST REPORT TUCHENG

Date: Aug.31,2020 Date of Receipt: Aug.24,2020

Report No.: TFF9H599 Quantity: 1PC Page Order/Pages: (P3/5) Ref. No.: NIL

Report Title: Curie Limited(U3104) Item: Mask

Address: No. 108, Ganhe Rd., Xitun Dist., Taichung City 407, Taiwan

Test Items		Test Results	Test Methods
Synthetic Blood Penetration	17	None Seen	EN 14683:2019
Pressure:120 mmHg (16.0 kPa)	18	None Seen	ISO 22609:2004
	19	None Seen	
	20	None Seen	
	21	None Seen	
	22	None Seen	
	23	None Seen	
	24	None Seen	
	25	None Seen	
	26	None Seen	
	27	None Seen	
	28	None Seen	
	29	None Seen	
	30	None Seen	
	31	None Seen	
	32	None Seen	

Note: Sample description is given by the client: Brandname: Curie

Model: Curie KV99 Face Mask

Hong Kong address: Unit C, 23F, Tsun Tung Factory Bldg 38-40

Chai Wan Kok St, Tsuen Wan. NT Hong Kong

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

Note: 1.This report is only responsible for the submitted sample(s), which will be kept for one month period.

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Authorized by president of Taiwan Textile Research Institute

Jui-hung Kao

Director, Department of Testing and Certification

Department of Testing and Certification, Taiwan Textile Research Institute
No.6, Chengtian Rd., Tucheng Dist., New Taipei City 23674, Taiwan (R.O.C.)
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TTRI 財團法人紡織產業綜合研究所 Taiwan Textile Research Institute

TEST REPORT TUCHENG

Date: Aug.07,2020 Date of Receipt: Jul.27,2020

Report No.: TAG9G706 Quantity: 1PC Page Order/Pages: (P3/5) Ref. No.: NIL

Report Title: Curie Limited(U3104) Item: Mask

Address: No. 108, Ganhe Rd., Xitun Dist., Taichung City 407, Taiwan

Test Items		Test Results	Test Methods
Synthetic Blood Penetration	17	None Seen	ASTM F2100-2019 9.4
Pressure:160 mmHg	18	None Seen	ASTM F1862-2017
	19	None Seen	
	20	None Seen	
	21	None Seen	
	22	None Seen	
	23	None Seen	
	24	None Seen	
	25	None Seen	
	26	None Seen	
	27	None Seen	
	28	None Seen	
	29	None Seen	
	30	None Seen	
	31	None Seen	
	32	None Seen	

Note: Sample description is given by the client: Brandname: Curie
Model: Curie KV99 Face Mask
Hong Kong address: Unit C, 23F, Tsun Tung Factory Bldg 38-40
Chai Wan Kok St, Tsuen Wan. NT Hong Kong

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

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TEST REPORT TUCHENG

Date: Aug.31,2020 Date of Receipt: Aug.24,2020

Report No.: TFF9H598 Quantity: 1PC Page Order/Pages: (P4/5) Ref. No.: NIL

Report Title: Curie Limited(U3104) Item: Mask

Address: No. 108, Ganhe Rd., Xitun Dist., Taichung City 407, Taiwan

Test Items		Test Results	Test Methods
Bacterial Filtration	1	99.9	ASTM F2100-2019 9.1
Efficiency (BFE)(%)	2	99.9	ASTM F2101-2019
Staphylococcus aureus	3	> 99.9	
ATCC 6538	4	99.9	
	5	99.9	

Note: Control average: 2640 CFU.

Note: Mean particle size: 2.8 μm.

Note: Testing side: outside of specimen.

Note: Testing area: 39.5 cm^2.

Note: Flow rate : 28.3 L/min.

Note: Sample description is given by the client: Brandname: Curie
Model: Curie KV99 Face Mask
Hong Kong address: Unit C, 23F, Tsun Tung Factory Bldg 38-40
Chai Wan Kok St, Tsuen Wan. NT Hong Kong

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

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TEST REPORT TUCHENG

Date: Aug.31,2020 Date of Receipt: Aug.24,2020

Report No.: TFF9H599 Quantity: 1PC Page Order/Pages: (P4/5) Ref. No.: NIL

Report Title: Curie Limited(U3104) Item: Mask

Address: No. 108, Ganhe Rd., Xitun Dist., Taichung City 407, Taiwan

Test Items		Test Results	Test Methods
Bacterial Filtration	1	> 99.9	EN 14683:2019 Annex B
Efficiency (BFE)(%)	2	99.9	
Staphylococcus aureus	3	99.9	
ATCC 6538	4	> 99.9	
	5	99.9	

Note: Control average: 2640 CFU.

Note: Mean particle size: 2.8 μm.

Note: Testing side: outside of specimen.

Note: Testing area: 39.5 cm^2.

Note: Flow rate : 28.3 L/min.

Note: Sample description is given by the client: Brandname: Curie

Model: Curie KV99 Face Mask

Hong Kong address: Unit C, 23F, Tsun Tung Factory Bldg 38-40

Chai Wan Kok St, Tsuen Wan. NT Hong Kong

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

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TTRI 財團法人紡織產業綜合研究所 Taiwan Textile Research Institute

TEST REPORT TUCHENG

Date: Aug.07,2020 Date of Receipt: Jul.27,2020

Report No.: TFF9G707 Quantity: 1PC Page Order/Pages: (P5/6) Ref. No.: NIL

Report Title: Curie Limited(U3104) Item: Mask

Address: No. 108, Ganhe Rd., Xitun Dist., Taichung City 407, Taiwan

Test Items		Test Results	Test Methods
Microbial cleanliness (cfu/g)	1	13.7	EN 14683:2019 EN ISO 11737-1:2018
	2	10.6	
	3	4.4	
	4	10.1	
	5	11.0	

Note: Sample description is given by the client: Brandname: Curie
Model: Curie KV99 Face Mask
Hong Kong address: Unit C, 23F, Tsun Tung Factory Bldg 38-40
Chai Wan Kok St, Tsuen Wan. NT Hong Kong

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

Note: 1.This report is only responsible for the submitted sample(s), which will be kept for one month period.
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Bacterial Filtration Efficiency (BFE) in ASTM F2101

Proven that Curie technology can effectively filter bacteria (>99%)

香港公開大學
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政府創辦，多元創新
Government established · Diversified and innovative

TEST REPORT

Applicant: Curie Limited
Room C, 23/F,
Tsuen Tung Factory Building,
38-40 Chai Wan Kok Street,
Tsuen Wan,
New Territories,
Hong Kong

Report number: IRITS202005150001

Date: 15 May 2020

Attn.: Aldrin Or

Sample Description as Declared:

No. of Sample:	TWO (2) pieces of received material in zipper bag packaging
Sample Description:	Curie Ultrahigh- Efficiency Viral Filter
Colour:	White
Date Received:	8 May 2020
Testing Period:	9 – 14 May 2020
Tests Conducted:	As requested by the Applicant, with the details as follow:

Testing Summary: The sample being tested was conditioned for a minimum of 4 hour at 21 ± 5 °C and relative humidity of 65 ± 5 %. The bacterial filtration efficiency (BFE) test was performed by applying a spray of challenge bacterium *Staphylococcus aureus* in peptone water (approximately 2,200 colony forming units per spray) using a trigger sprayer. The sprayed aerosol was then drawn through the material being tested following by a tryptic soy agar plate under vacuum (flow rate: 100 Litres per minute). Number of *Staphylococcus aureus* colonies formed on the tryptic soy agar plate were counted after incubated at 37 ± 2 °C for 48 ± 4 hr. The BFE test procedure was modified from ASTM F2101: 2019.

For and on behalf of
Institute for Research in Innovative Technology & Sustainability
The Open University of Hong Kong

Dr. Eric Tung-po Sze
Director

香港公開大學
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Report number: IRITS202005150001

Date: 15 May 2020

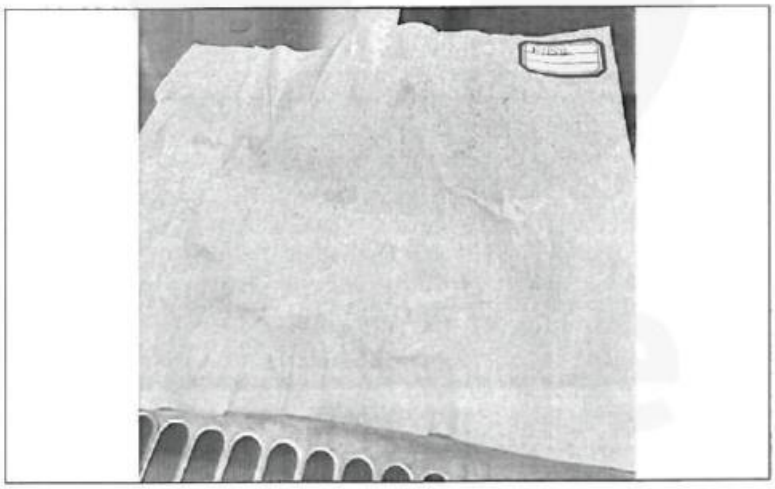
Results:

Test Sample Number

Test Sample Number	Bacterium Colonies Formed
#1	N.D.[a]
#2	N.D.[a]
Negative Control	N.D.[a]

[a] None Detected (N.D.) – There were no detected bacterium colony of *Staphylococcus aureus* found.

Sample Photo:



<End of Test Report>

Standard Guide for Accelerated Ageing of Sterile Barrier Systems for Medical Devices in ASTM F1980-16
Bacterial Filtration Efficiency (BFE) in ASTM F2101

Proven that Curie technology can effectively filter bacteria (>99%), after conditioning KV99 masks in 120°C for 48 hours, to simulate storing in room temperature for 5 years

香港公開大學
THE OPEN UNIVERSITY OF HONG KONG
科技學院 School of Science and Technology

TEST REPORT

Applicant: Curie Limited
Room C, 23/F,
Tsuen Tung Factory Building,
38-40 Chai Wan Kok Street,
Tsuen Wan,
New Territories,
Hong Kong

Report number: IRITS2020007030001

Date: 3 July 2020

Attn.: Aldrin Or

Sample Description as Declared:

No. of Sample:	TWO (2) pieces of composite material for face mask in zipper bag packaging Curie KV99
Colour:	White
Date Received:	15 June 2020
Testing Period:	16 – 24 June 2020
Tests Conducted:	As requested by the Applicant, with the details as follow:

Testing Summary: The sample(s) were conditioned at an acceleration temperature of 120 °C for 48 hours, followed by pre-conditioning at a minimum of 4 hour at 21 ± 5 °C and relative humidity of 65 ± 5 %. Bacterial filtration efficiency (BFE) test was then performed by spraying the samples with an aerosol of challenge bacterium *Staphylococcus aureus* in peptone water using a nebulizer. The aerosol was then drawn through the samples following by a tryptic soy agar plate under vacuum (flow rate: 100 Litres per minute). Number of *Staphylococcus aureus* colonies formed on the tryptic soy agar plate were counted after incubated at 37 ± 2 °C for 48 ± 4 hr. The BFE test procedure was modified from ASTM F2101: 2019.

For and on behalf of
Institute for Research in Innovative Technology & Sustainability
The Open University of Hong Kong

Dr. Eric Tung-po Sze

香港公開大學
THE OPEN UNIVERSITY OF HONG KONG
科技學院 School of Science and Technology

Report number: IRITS2020007030001

Date: 3 July 2020

Results:

Test Sample Number	Bacterium Colonies Formed	Bacterial Filtration Efficiency
#1	N.D.[a]	> 99 %
#2	N.D.[a]	> 99 %
Negative Control	N.D.[a]	N/A[b]

[a] None Detected (N.D.) – There were no detected bacterium colony of *Staphylococcus aureus* found

[b] N/A – Not Applicable

Remark: The time and temperature selected for the acceleration conditioning were based on ASTM Standard F1980-16 Appendix X1. Accelerated aging of polymers, which are equivalent to five year of room-temperature (20 °C) aging, with an aging factor Q_{10} = 2.0.

Sample Photos:

<End of Test Report>

Determination of Antibacterial Activity of Textile Products BS EN ISO 20743

Proven that Curie technology can effectively kill bacteria (>99%) · In less than 60 seconds.

香港公開大學
THE OPEN UNIVERSITY OF HONG KONG
科技學院 School of Science and Technology

TEST REPORT

Applicant: Curie Limited
Room C, 23/F,
Tsuen Tung Factory Building,
38-40 Chai Wan Kok Street,
Tsuen Wan,
New Territories,
Hong Kong

Report number: IRITS2020007130001R1

Date: 23 July 2020

Attn.: Aldrin Or

Sample Description as Declared:

No. of Sample:	ONE (1) piece of textile material in zipper bag packaging said to be RT-2007-T0430-DC020
Colour:	White
Date Received:	21 May 2020
Testing Period:	2 – 10 July 2020
Tests Conducted:	As requested by the Applicant to determine the antibacterial activity of the sample with reference to BS EN ISO 20743: 2013 Clause 8.2 Transfer method, with the following deviation:

- Shake-out the bacteria from specimens using peptone water instead of neutralizing solution.

For and on behalf of
Institute for Research in Innovative Technology & Sustainability
The Open University of Hong Kong

Dr. Eric Tung-po Sze
Director

香港公開大學
THE OPEN UNIVERSITY OF HONG KONG
科技學院 School of Science and Technology

Report number: IRITS2020007130001R1

Date: 23 July 2020

Results:

Specimen	Conditions	Number of bacteria[a] (CFU per specimen)
#1	Shake-out before incubation	0
#2	Shake-out after incubation	0

[a]1 millilitre of an inoculum of *Staphylococcus aureus* with concentration of 1×10^6 CFU/ml to 3×10^6 CFU/ml was applied onto an agar plate in the transfer method, where each specimen was set on the agar surface and weigh down with a 200 g stainless-steel cylinder for 60 s ± 5 s to transfer the microbial content. Incubation Measurement of the number of bacteria colonies was conducted in accordance with the plate count method specified in Annex C of BS EN ISO 20743:2013.

Opinion(s) and Interpretation(s): Based on the results obtained above, the specimens demonstrated effective antibacterial property to kill bacteria during transfer phase of the experiment.

Note: This Report replaces Report number IRITS2020007130001, which has been obsoleted.

<End of Test Report>

Determination of Antiviral Activity of Textile Products BS ISO 18184

Proven that Curie technology can effectively kill Influenza A Virus Subtype H3N2 (>99.99%)

广微测 Gmicro Testing

中国认可 国际互认 检测 TESTING CNAS L1747

GUANGDONG DETECTION CENTER OF MICROBIOLOGY

REPORT FOR ANALYSIS

Report №.	2020FM20686R01E
Name of Sample	Curie Ultrahigh-Efficiency Viral Filter for KV-99
Applicant	Shenzhen Qianhai e-Cycle Trading Co.,Ltd.
Test Type	Entrustment Test

Address: Building 66, No.100 Central Xian Lie Road, Guangzhou, China

Postcode: 510070

Tel: +86 20 87137666

Fax : +86 20 87137668

Website : www.gddcm.com

GUANGDONG DETECTION CENTER OF MICROBIOLOGY

REPORT FOR ANALYSIS

Report №.:2020FM20686R01E Verification Code: 03658924

Name of Sample	Curie Ultrahigh-Efficiency Viral Filter for KV-99	Test Type	Entrustment Test
Applicant	Shenzhen Qianhai e-Cycle Trading Co.,Ltd.	Address	2/F,Building B2，Yintian Industrial Area，Xixiang Street，Baoan District，Shenzhen Guangdong，China
Sample Source	Submitted for Testing by the Applicant	Sample Quantity	260cm*2m
Spec and Lot № of Sample	40g;1001	State and Characteristic	Flaky
Sample Received Date	2020-07-15	Test Completion Date	2020-07-28
Test Standard and Method	ISO 18184：2014（E）		
Item Tested	Antiviral activity test		
Test Conclusion	The test data of the sample(s) is attached to the page(s) of this report. Issue Date：2020-08-13 (Official Seal)		
Remarks	1.Manufacturer: Curie Limited. (provided by the applicant) 2.Trademark: Curie; The date of production: 2020-06-01. (provided by the applicant)		

Editor: Chen Yingxing **Verifier:** Li Suquan **Approver:** Xie Xiaobao

GUANGDONG DETECTION CENTER OF MICROBIOLOGY

ANALYSIS AND TEST RESULT

Report №.: 2020FM20686R01E

Virus and host cell	No.	The logarithm of infectivity titre value immediate after inoculation of the reference specimen ($lgTCID_{50}$/bottle)	The logarithm of infectivity titre value after 2h contacting with the reference specimen ($lgTCID_{50}$/ bottle)	The logarithm of infectivity titre value after 2h contacting with the test specimen ($lgTCID_{50}$/ bottle)
H3N2 *Influenza A virus* Host cell: MDCK	1	7.05	6.50	2.10
	2	6.97	6.63	2.30
	3	7.10	6.59	2.30
$lgTCID_{50}$/ bottle Average		7.04	6.57	2.33
Logarithm of antiviral activity		4.34		
Antiviral activity rate（%）		99.99		

（Blank below）

Notice Items

1. The Test report is invalid if not affixed with Authorized Stamp of Test and Paging Seal.
2. The Test report is invalid without signature of verifier and approver.
3. The Test report is invalid if being supplemented, deleted or altered.
4. Without prior written permission, the report cannot be reproduced, except in full.
5. Unless otherwise stated, the results shown in this test report refer only to the sample(s) submitted.
6. Any dispute of the report must be raised to the testing body within 15 days after the report is received, exceeding which the dispute will not be accepted。
7. For the tested sample(s) submitted by the applicant, the sample information in the test report is provided by the applicant and the laboratory is not responsible for its authenticity.

Determination of alkylphenols (AP) of Textile Products EN ISO 21084:2019

Proven that Alkylphenols (AP) is not detected from Curie technology

Detection and Determination of Alkylphenol Ethoxylates (APEO) of Textile Products EN ISO 18254:2016

Proven that Alkylphenol Ethoxylates (APEO) is not detected from Curie technology

TEST RESULT

Alkylphenols (AP) Content Test

Test Method I : For Textile & Leather:
EN ISO 21084

Test Method II : For Polymers and other materials:
Organic solvent extraction, analysis with reference to EN ISO 21084.

Tested Item(s) : I001 White fabric with transparent adhesive

Maximum Limit:	**100 mg/kg (sum)**

Tested Item(s)	**Test Method**	**Result**			**Conclusion**
		Detected Analyte(s)	**Conc.**	**Unit**	
I001	I	ND	ND	mg/kg	PASS

Note:
ND = Not detected ">" = More than Conc. = Concentration
ppm = part(s) per million = mg/kg mg/kg = milligram(s) per kilogram
Reporting Limit (mg/kg) : Sum (OP & NP) : 10

Remark:
- The list of alkylphenols is summarized in table of Appendix.

Alkylphenol Ethoxylates (APEO) Content Test

Test Method I : For Textile and Other materials:
With reference to EN ISO 18254-1, analysis by Liquid Chromatograph Mass Spectrometer (LC-MS)

Test Method II : For Leather:
With reference to EN ISO 18218-1 and EN ISO 18254-1

Tested Item(s) : I001 White fabric with transparent adhesive

Maximum Limit:	**Others: 100 mg/kg (Sum)** **Recycled materials: 1000 mg/kg (Sum)**

Tested Item(s)	**Test Method**	**Result**			**Conclusion**
		Detected Analyte(s)	**Conc.**	**Unit**	
I001	I	ND	ND	mg/kg	PASS

Note:
ND = Not detected ">" = More than Conc. = Concentration
ppm = part(s) per million = mg/kg mg/kg = milligram(s) per kilogram
Reporting Limit (mg/kg) : Sum (OPEOs & NPEOs) : 20

Remark:
- The list of alkylphenol ethoxylates is summarized in table of Appendix.

Determination of Formaldehyde - Free and Hydrolysed Formaldehyde of Textile Products

EN ISO 14184:2011 / JIS L 1041

Proven that Formaldehyde is not detected from Curie technology, and it reach safety level for Type 1 – Baby < 36 Months

TEST RESULT

Formaldehyde Content Test

Test Method I : Textiles & Other Materials: EN ISO 14184-1
Test Method II : Leather: ISO 17226:2 and/or ISO 17226-1
Test Method III : Glue & 0-3 years old products: JIS L 1041: 2011 Method A
Test Method IV : Carpets and mats: GB 18587 Grade B.

Tested Item(s) : I001 White fabric with transparent adhesive

Maximum Limit:	**Type I**	**For baby < 36 months: 16 mg/kg**
	Type II	**Others: 75 mg/kg**
	Type III	**Carpets and mats : < 0.050 mg/m²/h**

Tested Item(s)	Type	Test Method	Result	Unit	Conclusion
I001	I	III	ND	mg/kg	PASS

Note:
ND = Not detected ">" = More than
ppm = part(s) per million = mg/kg mg/kg = milligram(s) per kilogram
Reporting Limit : 16 mg/kg (Method I, II, III), 0.050 mg/m²/h (Method IV)

Determination of Tetrachlorophenol-, Trichlorophenol-, Dichlorophenol-, Monochlorophenol-Isomers and Pentachlorophenol Content of Textile Products

DIN EN ISO 17070:2015 / 64 LFBG B 82.02-08 (Modified)

Proven that Chlorophenols Content and Ortho-Phenylphenol (OPP) are not detected from Curie technology

TEST RESULT

Chlorophenols Content Test

Test Method : With reference to ISO 17070:2015 or 64 LFBG B 82.02-08 (Modified). Potassium hydroxide extraction, derivatisation and analysis by Gas Chromatograph Mass Spectrometer (GC-MS).

Tested Item(s) : I001 White fabric with transparent adhesive

Maximum Limit:	**0.5 mg/kg (Each)**

Tested Item(s)	**Result**			**Conclusion**
	Detected Analyte(s)	**Conc.**	**Unit**	
I001	ND	ND	mg/kg	PASS

Note:
ND = Not detected
ppm = part(s) per million = mg/kg
Reporting Limit (mg/kg) : Each : 0.5
">" = More than
mg/kg = milligram(s) per kilogram

Remark:
- The list of chlorophenols is summarized in table of Appendix.

Ortho-phenylphenol (OPP) Test

Test Method : 1 M KOH extraction, 16 hours at 90 degrees C, derivatization and analysis § 64 LFGB B 82.02-08 or DIN EN ISO 17070:2015.

Tested Item(s) : I001 White fabric with transparent adhesive

Maximum Limit:	**1000 mg/kg**

Tested Item(s)	**Result**	**Unit**	**Conclusion**
I001	ND	mg/kg	PASS

Note:
ND = Not detected
ppm = part(s) per million = mg/kg
Reporting Limit (mg/kg) : 100
">" = More than
mg/kg = milligram(s) per kilogram

Determination of the Phthalate Content of Textile Products EN ISO 14389: 2014 / US CPSC-CH-C1001-09.4

Proven that Phthalate Content are not detected from Curie technology

Phthalates Content Test

Test Method I : Textile: CPSC-CH-C1001-09.4 and EN ISO 14389: 2014.

Test Method II : Others: CPSC-CH-C1001-09.4, analysis by Gas Chromatograph Mass Spectrometer (GC-MS).

Tested Item(s) : I001 White fabric with transparent adhesive

Maximum Limit:	**500 mg/kg (Each)** **1000 mg/kg (Sum)**

Tested Item(s)	Test method	Result			Conclusion
		Detected Analyte(s)	Conc.	Unit	
I001	I	ND	ND	mg/kg	PASS

Note:

ND = Not detected
ppm = part(s) per million = mg/kg
Reporting Limit (mg/kg) : Each : 50

">" = More than
mg/kg = milligram(s) per kilogram

Conc. = Concentration

Remark:

- The list of phthalates is summarized in table of Appendix.